

EXHIBIT 47

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF NEW JERSEY

IN RE: JOHNSON & JOHNSON
TALCUM POWDER PRODUCTS
MARKETING, SALES PRACTICES,
AND PRODUCTS LIABILITY
LITIGATION

Case No. 16-2738

THIS DOCUMENT RELATES TO (FLW) (LHG)
ALL CASES
MDL Docket No. 2738

Friday, January 11, 2019

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The video deposition of SHAWN LEVY, Ph.D.,
taken pursuant to notice, was held at the
Embassy Suites Huntsville, 850 Monroe Street
S.W., Huntsville, Alabama, commencing at
approximately 9:04 a.m., on the above date,
before Lois Anne Robinson, Registered Diplomat
Reporter, Certified Realtime Reporter, and
Notary Public for the State of Alabama.

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1 A P P E A R A N C E S - (continued)

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1 VIDEOGRAPHER:

2 We are now on the record. My name is
3 Julie Robinson. I'm a videographer representing
4 Golkow Litigation Services.

5 Today's date is January 11th, 2019, and
6 the time is 9:04 a.m.

7 This video deposition is being held in
8 Huntsville, Alabama, in the matter of
9 Johnson & Johnson Talcum Powder Product Marketing,
10 Sales Practices, and Products Liability
11 Litigation, MDL Docket Number 2738.

12 The deponent is Dr. Shawn Levy.

13 Counsel will be noted on the
14 stenographic record.

15 The court reporter is Lois Robinson,
16 who will now swear in the witness.

17 SHAWN LEVY, Ph.D.,
18 the witness, after having first been
19 duly sworn to tell the truth, the whole truth,
20 and nothing but the truth, was examined and
21 testified as follows:

22 EXAMINATION

23 BY MS. BROWN:

24 Q Good morning, Dr. Levy.

1 A Good morning.

2 Q My name is Alli Brown. I represent
3 Johnson & Johnson, and I'll start with some
4 questions for you here today.

5 Dr. Levy, have you ever been deposed
6 before?

7 A Yes.

8 Q And tell me, how many times?

9 A In a setting like this, once.

10 Q Okay. What was the nature of that
11 deposition?

12 A It was a patent litigation case.

13 Q Were you serving as an expert witness
14 in that case?

15 A I was.

16 Q Were you hired by the plaintiffs or the
17 defendants?

18 A The plaintiffs.

19 Q And, just generally, what were the
20 issues in that case?

21 A It was entirely focused on evaluation
22 of prior art in the genomic space.

23 Q And any time --

24 And do you remember the name of that

1 case, by the way?

2 A I don't. It was, gosh, twelve years
3 ago or so.

4 Q I see.

5 Did that case go to trial?

6 A Not that I'm aware of.

7 Q Have you ever testified at trial?

8 A I have not.

9 Q Okay. And other than that one patent
10 case you just described for us, were there other
11 depositions that you've given?

12 A No.

13 Q And I think, when you started to answer
14 the question in the beginning, you said "in a
15 setting like this." Is there another time, in
16 your mind, where you've given testimony under
17 oath?

18 A No, not under oath. That's why I
19 was --

20 So I've had a number of meetings, all
21 limited to the patent space of mainly prior art
22 discussions, where there's been representatives
23 from both sides where we were having a
24 discussion. But it wasn't a formal deposition

1 with a court reporter, under oath, et cetera.

2 Q Understood.

3 So this would then be the second time
4 you've been deposed in a setting like this.

5 A Correct.

6 Q Is that fair?

7 Okay. So a few ground rules that you
8 may already be familiar with from your prior
9 experience. First, we'll try not to speak over
10 each other. Is that fair?

11 A That's fair.

12 Q That way, our court reporter can get
13 down all my questions and all your answers.

14 Okay?

15 A (Nods affirmatively.)

16 Q If you don't understand a question of
17 mine, will you let me know?

18 A I will.

19 Q Okay. Try to verbalize your answers,
20 too, so our court reporter can take them down.

21 Okay?

22 A Understood.

23 Q Okay. If you need a break, let me
24 know, and we'll be happy to accommodate you.

1 Do you understand you're under oath
2 here today, same as if you were in a court of
3 law?

4 A I do.

5 Q Okay. I am --

6 And, before we get started, Doctor, I
7 see you have a couple of items in front of you,
8 and I want to identify what we have for the
9 record.

10 To your right is an iPad that is
11 showing the realtime of my questions and your
12 answers. Will you be using that to assist you in
13 your testimony here today?

14 A Yes.

15 Q Okay. In front of you you have a
16 laptop computer.

17 A (Nods affirmatively.)

18 Q Will you be using that to assist you in
19 your testimony?

20 A Yes.

21 Q And tell me, is this your laptop?

22 A It is not.

23 Q Okay. Whose laptop is it?

24 A The -- the attorneys I've been working

1 with.

2 Q Okay. In front of you is the
3 plaintiffs' lawyer's laptop. Is that right?

4 A That's right.

5 Q Okay. And what is contained on the
6 plaintiffs' lawyer's laptop?

7 MS. O'DELL:

8 I think I'd probably be better to speak
9 to it.

10 MS. BROWN:

11 No, no. Let's get it from the witness,
12 and then if you want to make a statement for the
13 record, of course.

14 Q Let's -- let's get your understanding
15 of what's on this laptop in front of you.

16 A Other than what's on the USB drive that
17 I've been using, I -- I don't have any knowledge
18 of what's on it.

19 Q Okay. Do you know what's on the USB
20 drive?

21 A I do.

22 Q What's that?

23 A It's a collection of literature cited
24 in reliance literature list that -- from

1 my -- from my report.

2 Q Did you put together the items that are
3 contained on the USB drive that you have in front
4 of you?

5 MS. O'DELL:

6 Object to the form.

7 A Yes.

8 MS. BROWN:

9 Q Is that your USB drive?

10 A No. I put together the list.

11 As far as who moved the files and
12 organized the files on the USB, that, I don't
13 know.

14 Q Okay. Are all of the files on that USB
15 drive documents that you considered in connection
16 with your opinion in this case?

17 A They are.

18 Q Any other materials in front of you
19 that you'll be using to assist you in your
20 testimony here today?

21 A There's a -- I have a hard copy of my
22 report.

23 Q Did you prepare that hard copy binder?

24 A No.

1 Q Who -- who did?

2 A My -- the -- the attorneys I've been
3 working with. So I -- they -- they provided the
4 printout and the nice binder that it's in.

5 Q Okay. Did you, Doctor, make any notes
6 on the report that you have in front of you?

7 A No.

8 Q Okay. I'm gonna hand you what we have
9 marked as Exhibit 1 to your deposition, which is
10 a notice of your deposition.

11 (DEPOSITION EXHIBIT NUMBER 1
12 WAS MARKED FOR IDENTIFICATION.)

13 MS. BROWN:

14 Q And I'll ask, is this something that
15 you have ever seen before?

16 A Yes.

17 Q When did you see it?

18 A I'd have to review my email, but it was
19 some -- sometime ago, some weeks ago.

20 Q Okay. Have you brought any --

21 And you understand that this Notice of
22 Deposition that we've marked as Exhibit 1
23 requests that you bring certain documents with
24 you here today?

1 A Yes.

2 Q Okay.

3 MS. O'DELL:

4 Let me just insert for the record,
5 we've objected to certain requests contained in
6 the notice, and objections have been served, and
7 materials have been brought to this deposition
8 consistent with those objections.

9 MS. BROWN:

10 And we are in receipt of your
11 objections.

12 Q And your counsel for the plaintiffs
13 represented that some materials have been brought
14 to the deposition. Do you have any materials
15 with you responsive to this notice?

16 A Well --

17 MS. O'DELL:

18 I'll provide to you invoices that are
19 responsive to the Notice, and there are materials
20 that Dr. Levy has seen since his report was
21 served, and -- and those are copies.

22 MS. BROWN:

23 Thank you, counsel.

24 Q So, Doctor, let's start --

1 Thank you.

2 -- by marking these, and I'll ask you
3 some questions about what we have.

4 (DEPOSITION EXHIBIT NUMBER 3
5 WAS MARKED FOR IDENTIFICATION.)

6 MS. BROWN:

7 Q I'll mark as Exhibit 3 to your
8 deposition two invoices counsel for plaintiffs
9 just handed me, one dated May 2nd, 2018, and the
10 other dated January 8th, 2019. And we only have
11 one copy, so let me hand it to you and ask you,
12 are these invoices that you created, Doctor?

13 A They are.

14 Q Okay. And I want to take that back for
15 one second.

16 Looks like the first entry on your
17 invoice is dated May 16th, 2017. Does that sound
18 right to you?

19 A That sounds right.

20 Q When were you first approached about an
21 involvement in this case?

22 A Earlier in 2017.

23 Q Okay. And who approached you?

24 A Leigh and Jennifer. I'd have to verify

1 in my email whom I may have heard from first.

2 Q Okay. And Leigh and Jennifer are
3 counsel for plaintiffs in this litigation; is
4 that right?

5 A That's right.

6 Q And did they -- had you known them
7 prior to receiving contact early in 2017 --

8 A No.

9 Q -- from plaintiffs' lawyers?

10 A I -- I did not know them.

11 Q Did they call you at your place of
12 business?

13 A I believe the first contact was email.
14 But, ultimately, yes.

15 Q Okay. And was there any connection,
16 meaning did someone refer the plaintiffs' lawyers
17 to you, or do you know?

18 A I don't know.

19 Q Do you have any idea how the
20 plaintiffs' lawyers found you?

21 A I do not.

22 Q Okay. It looks like, Doctor, that
23 these two invoices have a total of 33 hours.
24 Does that sound right to you?

1 A It does.

2 Q Looks like something's blacked out on
3 the second page of the invoices. Do you know
4 what that is?

5 MS. O'DELL:

6 I'll just say that redactions were made
7 by counsel. They referenced the subject matter
8 of conversations between Dr. Levy and counsel,
9 and those have been redacted because of work
10 product privilege.

11 MS. BROWN:

12 Okay.

13 Q Is it fair, Doctor, that you've spent a
14 total of 33 hours forming your opinions in this
15 case?

16 A That's fair.

17 Q Okay. Do you have any additional
18 invoices that you plan to submit to the lawyers
19 for the plaintiffs?

20 A Yes.

21 Q Okay. And can you ballpark for me how
22 much additional time you've spent since the last
23 entry here, which appears to be December 12th,
24 2018?

1 A There's probably another -- not
2 including this morning -- roughly 15 hours.

3 Okay. I'll hand you, Doctor, what we
4 have marked as Exhibit 4 to your deposition.
5 This is another document counsel for the
6 plaintiffs just handed me.

7 (DEPOSITION EXHIBIT NUMBER 4
8 WAS MARKED FOR IDENTIFICATION.)

9 MS. BROWN:

10 Q Would you identify that for the record,
11 please.

12 A This is a printed copy from a website
13 from the government of Canada discussing their
14 draft screening assessment of talc.

15 Q Okay. Is that something you've seen
16 before today?

17 A Yes.

18 Q When did you see it first?

19 A Sometime in December.

20 Q Did the lawyers for plaintiffs give it
21 to you?

22 A They did.

23 Q Okay. Your report in this case --
24 Can I have that back?

1 Your report in this case was served in
2 November of 2018; correct?

3 A Correct.

4 Q Fair to say, then, that Exhibit 4,
5 which you saw for the first time in December of
6 2018, did not inform the opinions contained in
7 your report?

8 A That's correct.

9 Q Okay. Did the -- does Exhibit 4
10 contain any information regarding chronic
11 inflammation as the proposed mechanism of ovarian
12 cancer induced by talc?

13 A I don't believe it does. I'd have to
14 review -- take a look at it to be sure.

15 MS. O'DELL:

16 And if you need to look at it, I'm sure
17 counsel will hand it to you.

18 MS. BROWN:

19 Q I'm handing you, Doctor --

20 MS. O'DELL:

21 Excuse me. If you need to look at it
22 to answer that question, you may.

23 A To be sure I'm accurate in my answer,
24 I'd like to take a look at that.

1 MS. BROWN:

2 Q Sure. Sitting here --

3 Hold on.

4 Sitting here today, you're not aware if
5 Exhibit 4 contains any information regarding the
6 proposed mechanism of chronic inflammation as a
7 cause for ovarian cancer?

8 MS. O'DELL:

9 Object to the question.

10 If you need to see the document,
11 Doctor, you may ask for it.

12 A Yeah. I'm not -- I'm not able to
13 answer it accurately without seeing the document.

14 (DEPOSITION EXHIBIT NUMBER 5
15 WAS MARKED FOR IDENTIFICATION.)

16 MS. BROWN:

17 Q Okay. Handing you what we've marked as
18 Exhibit 5, would you tell me what that is,
19 Doctor?

20 A This is another document from the
21 government -- government of Canada discussing the
22 potential risk of lung effects and ovarian cancer
23 from talc.

24 Q Is Exhibit 5 a final document, do you

1 know?

2 MS. O'DELL:

3 Object to the form.

4 A Yeah. That -- I don't -- I don't have
5 the information available to answer that
6 accurately.

7 MS. BROWN:

8 Q Have you seen Exhibit 5 prior to this
9 morning?

10 A I have.

11 Q When did you first see Exhibit 5?

12 A Similar in time to the earlier report
13 or this -- yes. Similar in time to the
14 earlier -- to the same document from Exhibit 4.

15 Q To the best of your recollection,
16 Doctor, you first saw Exhibit 5 after completing
17 your report in this matter; is that right?

18 A That is right.

19 Q Fair to say, then, that Exhibit 5 did
20 not inform the opinions contained in your MDL
21 report?

22 A That's correct.

23 Q Handing you, Doctor, what we've marked
24 as Exhibit 6 to your deposition, another document

1 counsel provided, counsel for plaintiffs provided
2 in response to your deposition notice.

3 (DEPOSITION EXHIBIT NUMBER 6
4 WAS MARKED FOR IDENTIFICATION.)

5 MS. BROWN:

6 Q Would you identify for the record
7 Exhibit 6?

8 A So this is a draft manuscript or
9 preprint manuscript that's been submitted for
10 peer review discussing the systematic review and
11 meta-analysis of the association between perineal
12 use of talc and risk of ovarian cancer.

13 Q Had you seen Exhibit 6 prior to this
14 morning?

15 A Yes.

16 Q When did you first see Exhibit 6?

17 A It was in December as well.

18 Q Exhibit 6 did not inform your opinions
19 in this matter. Fair?

20 A They did not inform the content of the
21 report.

22 Q Have you reviewed and analyzed Exhibit
23 6 since December?

24 A I have.

1 Q Does Exhibit 6 contain any information
2 regarding the proposed mechanism of chronic
3 inflammation?

4 A It does in reference, I believe. I'm
5 reminding myself if -- if it shared the same
6 materials that I had referenced in my report.

7 So, yes, it does.

8 Q Are you looking at a particular page,
9 Doctor?

10 A I am.

11 Q And would you identify that for the
12 record.

13 A I'm looking at page 23, beginning at
14 line 220.

15 Q And what information does Exhibit 6 at
16 page 23 contain regarding chronic inflammation?

17 A It discusses inflammation of the
18 epithelial ovarian surfaces in animal models and
19 provides two different references.

20 Q And were those references information
21 you considered in forming your opinions in this
22 case?

23 A Let me make sure of that.

24 Yes.

1 Q And would you state what they are for
2 the record, please?

3 A One reference is T.C. Hamilton, et al.,
4 The British Journal of Experimental Pathology,
5 from 1984.

6 And the other reference is "The
7 Pathology of Ovarian" -- "The Pathology of
8 Ovarian Cancer Precursors," which is a review of
9 R.E. Scully in the Journal of Cellular
10 Biochemistry, and that is a supplement from 1995.
11 The latter is not referenced in my report.

12 Q Have you reviewed the Scully paper in
13 connection with your opinions in this matter?

14 A Not specifically, no.

15 Q You have, however, reviewed the
16 Hamilton paper?

17 A Yes.

18 Q You would agree that the Hamilton paper
19 does not show inflammation leading to neoplastic
20 changes in animals?

21 MS. O'DELL:

22 Object to the form.

23 A I'd have to see the manu- -- or the
24 manuscript to answer your specific question

1 regarding neoplasm.

2 MS. BROWN:

3 Q Does the Hamilton paper support your
4 view that chronic inflammation is a plausible
5 mechanism for talc-induced ovarian cancer?

6 A It supports my opinion that
7 inflammation is a component in the progression to
8 ovarian cancer.

9 Q Is it your testimony that the Hamilton
10 paper supports your opinion that chronic
11 inflammation leads to neoplastic changes?

12 A No, not necessarily.

13 Q Okay. Tell me how it is that the
14 Hamilton paper supports your opinion that chronic
15 inflammation can cause ovarian cancer.

16 A Well, the -- so my opinion regarding --
17 that the role of inflammation in ovarian cancer
18 is not based on a single study, particularly one
19 that is now approaching or is now over 30 years
20 old.

21 Q Okay. Does --

22 A So it's a -- I reviewed the -- that
23 paper as well as a large number or the totality
24 of the available evidence stretching across many

1 years to develop the opinion that's represented
2 in my report.

3 Q Sure.

4 A And to that opinion is -- no one study
5 or one singular piece of information is the basis
6 of that opinion.

7 Q Okay. But, you know, having reviewed
8 Hamilton, that what Hamilton shows is that the
9 inflammation they saw in the animals was not
10 associated with neoplastic changes. Right?

11 MS. O'DELL:

12 Excuse me.

13 Doctor, if you'd like to -- to pull up
14 Hamilton, you may do that.

15 MS. BROWN:

16 Q And we'll certainly give you time to do
17 that, Doctor.

18 Sitting here today, do you recall that
19 to be the conclusion of Hamilton?

20 MS. O'DELL:

21 Object to the form.

22 You don't -- if you need to see the --

23 MS. BROWN:

24 Counsel --

1 MS. O'DELL:

2 -- paper in order to answer the
3 question --

4 MS. BROWN:

5 Counsel --

6 MS. O'DELL:

7 -- you may do that.

8 MS. BROWN:

9 Counsel, he is absolutely entitled to
10 get the paper. We're going to do that.

11 Q Sitting here today, do you recall --

12 MS. O'DELL:

13 But he is not --

14 MS. BROWN:

15 It's a fair question.

16 MS. O'DELL:

17 Is it not a fair question.

18 MS. BROWN:

19 I'm not gonna --

20 MS. O'DELL:

21 He's asking --

22 MS. BROWN:

23 -- do this with you.

24 MS. O'DELL:

1 Yes, you are. If he's asked to see the
2 paper, he gets to look at the paper. Because
3 this is not a situation where you can say, "Oh,
4 I'll show it to you later," ask all these
5 questions, try to get him to answer when he said
6 I want to see the paper and review it. That's
7 the way this works.

8 MS. BROWN:

9 Q Dr. Levy, can you answer the question
10 without looking at the paper?

11 MS. O'DELL:

12 Would you repeat the question just to
13 make sure we've got it?

14 MS. BROWN:

15 Yes. Would you please keep your
16 objections to form in accordance with the federal
17 rules?

18 MS. O'DELL:

19 My objections have been in accordance
20 with the federal rules.

21 MS. BROWN:

22 Q Dr. Levy, my question to you was
23 whether the Hamilton paper, the findings of the
24 Hamilton paper show that chronic inflammation led

1 to neoplastic changes. Do you recall that
2 question?

3 A I do recall the question.

4 Q Can you answer that question without
5 looking at the paper?

6 A I would need to look at the paper to
7 accurately answer your question.

8 Q Absolutely. Do you have a copy on your
9 computer?

10 A I do.

11 Q Okay. We'll mark it, so we're all on
12 the same page, as Exhibit 7.

13 (DEPOSITION EXHIBIT NUMBER 7
14 WAS MARKED FOR IDENTIFICATION.)

15 MS. BROWN:

16 Q Here's a hard copy, Doctor, if that
17 assists you.

18 Doctor, looking at the Hamilton article
19 that you have in front of you, does that refresh
20 you that the authors found no association between
21 the talc-induced changes and neoplasm?

22 A No. Their -- their conclusions were
23 that the talc-induced changes -- specifically
24 fibrosis and the papillary changes -- did not

1 appear to be a reaction to talc, but they -- I
2 don't see the specific inclusion that you asked
3 in the question regarding neoplasm.

4 Q I'm looking at page 103, Doctor, the
5 first full paragraph that begins "no evidence."

6 You with me?

7 A One moment. "No evidence of cellular,"
8 that paragraph?

9 Q Yes.

10 And, for the record, that paragraph
11 reads, "No evidence of cellular atypia or mitotic
12 activity was seen in the nonpapillary areas of
13 the surface epithelium of the injected ovaries
14 and in no ovary was there any evidence of frank
15 neoplasia."

16 Correct?

17 A It does read that way, yes.

18 Q And that was a conclusion of the
19 Hamilton article. Correct?

20 MS. O'DELL:

21 Object to the form.

22 A That was an observation of the Hamilton
23 article.

24 MS. BROWN:

1 Q The Hamilton article does not support
2 the theory that chronic inflammation leads to
3 neoplastic changes in the ovary. Fair?

4 MS. O'DELL:

5 Object to the form.

6 A The Hamilton article looked at an
7 interval of one month, eighteen months, in a rat
8 model. And, so, in the constraints of that
9 particular experimental design and given the
10 state of the art of the technology at the time,
11 the authors did not conclude of a significant
12 progression of ovarian cancer. But there's
13 clearly limitations in both their experimental
14 design and time course of the study to draw wide
15 conclusions.

16 MS. BROWN:

17 Q The conclusions of the Hamilton
18 article, Dr. Levy, do not support the hypothesis
19 that chronic inflammation from talcum powder
20 causes ovarian cancer. Would you agree?

21 A I would not.

22 Q The authors did not find that the
23 inflammation seen in Hamilton led to neoplastic
24 changes. True?

1 A The authors did not report observing
2 neoplastic change over the time course of the
3 given study.

4 Q Doctor, I'm handing you the report that
5 you've served in this case, which we'll mark as
6 Exhibit 2.

7 (DEPOSITION EXHIBIT NUMBER 2
8 WAS MARKED FOR IDENTIFICATION.)

9 MS. BROWN:

10 Q And I'd like you to -- I'd like to
11 direct you to page 14. I'd like to direct your
12 attention to the last paragraph of -- the last
13 sentence -- excuse me -- of the second full
14 paragraph that begins "additional studies."

15 Do you see that sentence, Doctor?

16 A What's the beginning of that paragraph
17 so I make sure I'm looking at the right one?

18 Q Sure. I'd like to direct you on page
19 14 of your report to the second full paragraph
20 that begins "In addition to epidemiologic
21 evidence."

22 Do you see that?

23 A I do.

24 Q The last paragraph, or the last

1 sentence of that paragraph in your report reads,
2 "Additional studies have also shown the effects
3 of talc on the immune response."

4 Do you see that sentence?

5 A I do.

6 Q And you cite the Hamilton article for
7 that proposition that we were just reviewing?

8 A Uh-huh.

9 Q True?

10 A True.

11 Q And the talc effects on the immune
12 response that were shown in Hamilton were not
13 effects that the authors observed led to
14 neoplastic changes. Correct?

15 MS. O'DELL:

16 Object to the form.

17 A I'm sorry. I'm not sure I understand
18 your question.

19 MS. BROWN:

20 Q Sure.

21 A Are you asking, if I could clarify, are
22 you -- are you asking if Hamilton is an
23 appropriate reference for the effects of talc on
24 the immune response or are you asking if

1 Hamilton's an appropriate reference for something
2 else?

3 Q In your report, you state that studies,
4 such as Hamilton, have shown effects of talc on
5 the immune response. Correct?

6 A That is correct.

7 Q And you said Hamilton as one of the
8 articles that supports that proposition. True?

9 A Of the immune response, that's true.

10 Q Okay. The immune response that was
11 observed in Hamilton was not an immune response
12 that led to cancer. Right?

13 A As -- as I stated earlier, on the time
14 course of the Hamilton study, the authors did not
15 report specifically to neoplastic change in the
16 rat or conclude or make that conclusion, nor did
17 they conclude that that was not a possibility
18 either.

19 Q And on page 14 of your report you have
20 two additional cites for that proposition;
21 correct?

22 A Correct.

23 Q And you know, Doctor, that neither of
24 those cites, Keskin or NTP, support the

1 hypothesis that chronic inflammation leads to
2 cancer in animals. Right?

3 A The --

4 MS. O'DELL:

5 Object to the form.

6 A The -- those two references were not
7 included in the report to provide the opinion or
8 conclusions that you just described.

9 MS. BROWN:

10 Q Because you know, Doctor, that there's
11 not a single animal study that shows that talc
12 causes changes in animals that leads to cancer;
13 right?

14 MS. O'DELL:

15 Object to the form.

16 A Could you -- could you phrase that
17 question again? Sorry.

18 MS. BROWN:

19 Q There is not a single animal study,
20 Doctor, that supports the opinion that chronic
21 inflammation caused by talc causes ovarian
22 cancer. Is that correct?

23 MS. O'DELL:

24 Object to the form.

1 A In my review of the literature, there
2 are a number of animal studies that support the
3 opinions in the report regarding the biological
4 plausibility of talc leading to or contributing
5 to neoplastic change.

6 MS. BROWN:

7 Q Are you aware of any animal studies,
8 Doctor, that show talc causing chronic
9 inflammation in animals that leads to neoplastic
10 or cancerous changes in the animals?

11 MS. O'DELL:

12 Object to the form. Compound.

13 A There is one 1971 study that I'm aware
14 of. I would have to review to remember the
15 author. That was an earlier seminal -- or a
16 earlier study that described the role of talcum
17 powder and the inflammatory change within the
18 ovary.

19 MS. BROWN:

20 Q Who's the author of that study, Doctor?

21 A I'm trying to think of where I have
22 that reference.

23 Q Why don't we put that to the side and
24 at a break we'll see if we can find that article

1 and then we can take a look at it. Okay?

2 A Uh-huh.

3 Q Okay. Getting back, then, Doctor, to
4 what we had marked as Exhibit 6, which is the
5 Taher paper, fair to say you reviewed that paper
6 after your report was submitted in this case?

7 A Yes.

8 Q Okay. And did you notice throughout
9 Taher's paper he makes reference to a number of
10 supplemental materials?

11 A Not specifically.

12 Q Are you in receipt from plaintiffs'
13 counsel of those supplemental materials?

14 A I'd have to -- you'd have to give me a
15 specific example, and I would be able to answer
16 you.

17 Q So, throughout the paper, the authors
18 make reference to a set of supplemental materials
19 that support their opinions. Do you recall that?

20 A I certainly recall the reference
21 materials to support their opinion. Whether they
22 were supplemental or otherwise, that doesn't
23 stand out to me.

24 Q Okay. And I'm not trying to be tricky.

1 I just want to know if you have those materials,
2 and, if so, I'm gonna request production of them.

3 A No. I -- I -- I don't believe that I
4 have the full list of reference -- of literature
5 cited from that -- from this paper --

6 Q Okay.

7 A -- now --

8 Q Now, Taher --

9 A -- but I'd have to check.

10 Q Sorry.

11 The Taher paper did not inform your --
12 the opinions contained in your report dated
13 November of 2018; correct?

14 A Correct, as written.

15 Q Okay. Are there any additional
16 documents that either you or your counsel have
17 brought with you here today in response to
18 Exhibit 1, the Notice of Deposition?

19 A So I'm not sure how to answer that
20 accurately, but I would say there's a -- I've
21 been provided with -- since the completion of my
22 report, I've been provided with reports from
23 other experts in the -- in the case.

24 Q Okay.

1 A And I have those on the -- available
2 electronically.

3 Q Okay. Were you provided with completed
4 versions of all the plaintiff experts in the MDL
5 proceeding?

6 A I can't speak to whether it was all,
7 but I have been provided with several.

8 Q Will you list for me the expert reports
9 you've been provided with?

10 A Sure.

11 Q Thank you.

12 A There are four on -- on this drive,
13 three -- I'm sorry. Two. Crowley and Longo.

14 Q Two reports from Dr. Crowley and two
15 reports from Dr. Longo?

16 MS. O'DELL:

17 I don't think that's what he said.

18 A No. I think there are two, two expert
19 reports, one from Dr. Crowley and one from
20 Dr. Longo.

21 MS. BROWN:

22 Q Okay. And the date of the Crowley
23 report, please?

24 A The -- according to the file, the

1 date -- the modified date is November 28, 2018.

2 Q And --

3 A Whether that was the written date, I --
4 I don't know.

5 Q And the Longo report, do you know the
6 date of that?

7 A It is listed as August 2nd, 2017, in
8 the title. And then there's a -- sorry. There's
9 a second Longo report, 2018, which has a
10 November 28, 2018, date. So my -- my apologies.
11 To correct, there are two expert reports from
12 Dr. Longo.

13 Q Got it.

14 MS. O'DELL:

15 So when you were talking about --

16 MS. BROWN:

17 Counsel, no. Huh-uh. No. We -- I'm
18 gonna ask questions, and he's gonna answer. We
19 are not going to have you testify. You are not
20 to testify about the expert reports.

21 MS. O'DELL:

22 I'm not gonna --

23 You asked him what the date of the
24 report was.

1 MS. BROWN:

2 He -- then he will answer, counsel.

3 You can't testify.

4 MS. O'DELL:

5 He gave you the date of the file -- the

6 file date --

7 MS. BROWN:

8 That's fine.

9 MS. O'DELL:

10 -- not the date --

11 MS. BROWN:

12 On redirect, you are welcome to clean

13 up whatever you need to. But we're not gonna

14 have your testimony on the record about dates of

15 expert reports.

16 A So, looking at the report itself, the

17 date of the Longo report is November 14th, 2018.

18 MS. BROWN:

19 Q And were you provided --

20 A The -- would you like the date of the

21 earlier report?

22 Q That would be terrific.

23 A It's August 2nd, 2017.

24 Q Great.

1 Were you provided the two Longo reports
2 and the Dr. Crowley report by plaintiffs'
3 counsel?

4 A Yes.

5 Q Do you recall when?

6 A Not specifically. It was, obviously,
7 by their date, sometime after their completion.
8 So the Crowley report and the later 2018 Longo
9 report were sometime in November or December
10 2018.

11 There's -- I've also had an opportunity
12 to review a number of -- several other expert
13 reports which are not with me today.

14 Q Do you have a listing of the additional
15 expert reports you were provided with?

16 A I'd have to -- I could certainly -- I'd
17 have to provide it. I don't, off the top of my
18 head, recall all of them. There was probably
19 approximately a dozen.

20 Q Were all of the plaintiff expert
21 reports sent to you at once?

22 MS. O'DELL:

23 Object to the form.

24 A I'm not -- I'm not certain.

1 MS. BROWN:

2 Q How did you receive them? Was it email
3 or hard copy?

4 A Neither. They were made available
5 through a shared storage.

6 Q And would you have received an email
7 alerting you to their existence on a shared file?

8 MS. O'DELL:

9 Dr. Levy, communications between
10 counsel are -- are subject to the work product
11 privilege.

12 So to the degree you're asking him to
13 convey what was in a communication, then I'll
14 object to that and instruct you not to discuss
15 communications between counsel.

16 MS. BROWN:

17 Q Which the question does not ask for,
18 Doctor.

19 MS. O'DELL:

20 I believe it does.

21 MS. BROWN:

22 Q Here's what I want to know. Did you
23 rely on any other expert reports in forming your
24 opinions in this case?

1 A To -- to my -- the content of my
2 report, no.

3 Q Did you receive the Crowley and two
4 Longo reports after you had already completed
5 your report in this case?

6 MS. O'DELL:

7 Object to the form.

8 A No. There was -- if I recall -- and
9 the -- at least the earlier Longo report -- and
10 I'd have to review the specifics -- at least the
11 earlier Longo report was reviewed and was
12 included in the content in the report.

13 And I would have to -- since the later
14 Longo report and then the final version of this
15 report were quite close together, I don't recall
16 if they overlapped or not. I'd have to review
17 the -- which references I used in here, which
18 will just take a moment.

19 So, yes, the -- I did include both
20 Longo reports.

21 Q The second Longo report was finalized
22 two days prior to your report. Is that right?

23 A Finalized, yes.

24 Q Did you see a draft of Longo's 2018

1 report?

2 A Yes. And the --

3 Q And did you --

4 A And as to when I saw the draft, I
5 believe it was -- and it was sometime in the fall
6 and/or when reports were being revised and
7 expanded as more literature became available.

8 Q Prior to Longo finalizing and signing
9 his expert report in the MDL, you had access to a
10 draft of that report; is that right?

11 MS. O'DELL:

12 Object to the form.

13 A I can't speak to -- to that accurately.

14 MS. BROWN:

15 Q I thought you just testified you saw a
16 version of the Longo 2018 report that was not
17 final. Is that correct?

18 MS. O'DELL:

19 Object to the form.

20 A I'd have to -- I'd have to review
21 my -- the -- the literature that I used for the
22 report to accurately answer your question.

23 MS. BROWN:

24 Q Well, your report doesn't say a draft,

1 and I'm wondering if you ever saw a non-finalized
2 copy of the Longo report.

3 A I didn't have an opportunity to compare
4 the finalized Longo report to a -- what may be a
5 draft or not to accurately answer your question
6 if I saw a draft that was substantially different
7 than what's referenced as the final.

8 Q There were two days between Longo
9 serving his report and you serving your report.
10 Does that help orient you as to whether you saw a
11 draft or you saw the final version?

12 A Certainly possible I saw the final
13 version.

14 Q How many hours did you spend on your
15 report in this case, Doctor?

16 A The initial draft of the report? The
17 initial writing of the report?

18 Q In total, how many hours did you spend
19 writing your report?

20 A It was 20 hours initially, and then it
21 would be -- it would be difficult to provide an
22 accurate answer for the rest of that. I would
23 say an additional few hours that I counted as
24 revision.

1 Q Did you type the expert report that
2 we've marked as Exhibit 2 yourself?

3 A I did.

4 Q Did you write all contents of Exhibit 2
5 yourself?

6 A I did.

7 Q Were there parts of your report that
8 you lifted from other published articles?

9 MS. O'DELL:

10 Object to the form.

11 A Could you describe "lifted"?

12 MS. BROWN:

13 Q Did you take the words of other authors
14 and put them in your expert report as Exhibit 2?

15 MS. O'DELL:

16 Object to the form.

17 A No. My -- my -- so my report is a
18 review of the available literature at the time
19 that the report was being developed. So, as
20 such, it describes that -- that literature.

21 As far as did I specifically copy words
22 from other reports, no.

23 MS. BROWN:

24 Q Did you work with another plaintiff

1 expert on the report that we've marked as
2 Exhibit 2?

3 A I did not.

4 Q Do you know who Dr. Zelikoff is?

5 A The name's not familiar to me.

6 Q Did you review a draft of
7 Dr. Zelikoff's report before submitting your own?

8 A I did not.

9 Q Do you think that --

10 A Not that I'm aware of.

11 Q Do you have any explanation as to why a
12 paragraph in your report is the same as a
13 paragraph in Dr. Zelikoff's report?

14 MS. O'DELL:

15 Object to the form.

16 A I -- without knowing -- without seeing
17 the paragraph in both reports would be -- I can't
18 comment.

19 MS. BROWN:

20 Q Let's mark as Exhibit 8 the expert
21 report of Dr. Judith Zelikoff, Ph.D.

22 (DEPOSITION EXHIBIT NUMBER 8

23 WAS MARKED FOR IDENTIFICATION.)

24 MS. BROWN:

1 Q Is this something you've seen --

2 Oh, sorry. Can I --

3 It's okay, actually. It will flag it
4 for you?

5 Is this a report that you've seen
6 before, Doctor?

7 A I'll have to see it before I answer.

8 Q I'm handing you what we've marked as
9 Exhibit 8, which is the expert report of
10 Dr. Judith Zelikoff. Is this one of the reports
11 that you reviewed prior -- you reviewed at all?

12 A I would have -- I would actually have
13 to review my -- the literature that I reviewed
14 in -- the totality of the literature that I
15 reviewed, which I could answer that after a
16 break, if necessary. But I don't recall,
17 specifically recall, this report under
18 Dr. Zelikoff's name. But it is certainly
19 possible that I may have seen...

20 Q Let's look at page 5 of your report,
21 Doctor.

22 A Okay.

23 Q And why don't you put that side by side
24 with page 20 of Dr. Zelikoff's report. And the

1 paragraph in Dr. Zelikoff's report that I want to
2 direct you to is the first full paragraph on
3 page 20 that begins "Genetic mutations."

4 Do you see that?

5 A I do.

6 Q And the paragraph of your report I want
7 to direct you to is the paragraph on page 5 that
8 begins "Both inherited."

9 Do you see that?

10 A I do.

11 Q Okay. The first sentence of that
12 paragraph in your report reads, "Both inherited
13 and acquired gene -- and acquired gene mutations
14 work together to cause cancer."

15 Do you see that?

16 A I do.

17 Q The third sentence of the paragraph I
18 directed you to in Dr. Zelikoff's report is
19 identical and reads, "Both inherited and acquired
20 gene mutations work together to cause cancer."

21 Do you see that?

22 A I do.

23 Q Those two sentences are exactly the
24 same, are they not?

1 A They are --

2 Q The next sentence --

3 A Just one moment, please. I'm just
4 making sure. Your question was are they exactly
5 the same, and I'm just confirming if they're
6 exactly the same.

7 So, yes, I agree they're exactly the
8 same.

9 Q You have reviewed them and satisfied
10 yourself that that -- those two sentences are
11 exactly the same; correct?

12 MS. O'DELL:

13 Object to the form.

14 A There's a single sentence in each
15 report that is exactly the same. But important
16 to comment that this single sentence is a -- is a
17 basic biological premise of cancer, and, so,
18 there's no surprise that two expert witnesses
19 offering opinions on the role of -- or the
20 biological plausibility or mechanisms of
21 development of cancer would introduce a
22 fundamental premise in the same manner.

23 MS. BROWN:

24 Q No surprise that you experts would have

1 one sentence that's the same? Is that what
2 you're saying?

3 MS. O'DELL:

4 Objection. That's not what he said.
5 Misrepresents his testimony.

6 A I'm saying that both would -- both
7 reports detail a fundamental aspect as they
8 would -- based on the current understanding of
9 the -- that both inherited and acquired gene
10 mutations work in concert to cause cancer.

11 MS. BROWN:

12 Q Look at the next sentence on page 20 of
13 Dr. Zelikoff's report. It reads as follows:
14 "Even if one has inherited a genetic mutation
15 that predisposes one to cancer," comma, "that
16 doesn't mean he or she is certain to get cancer."

17 Did I read that correctly?

18 A You did.

19 Q And let's go back to page 5 of your
20 report. Skip ahead, if you would -- one, two,
21 three -- four sentences to where you were and
22 find the sentence that begins "Even."

23 Are you with me?

24 A I am.

1 Q And your report at page 5 reads, "Even
2 if one has inherited a genetic mutation that
3 predisposes one to cancer," comma, "that doesn't
4 mean he or she is certain to get cancer."

5 Did I read that correctly?

6 A You did.

7 Q That's the exact same sentence we just
8 read in Dr. Zelikoff's report; correct?

9 A It is.

10 Q So now we have two sentences that are
11 exactly the same in your report and
12 Dr. Zelikoff's report. Correct?

13 MS. O'DELL:

14 Object to the form.

15 A You have two sentences that are written
16 the same but certainly not in precisely the same
17 context or organization in the total report.

18 MS. BROWN:

19 Q We have two sentences that are
20 word-for-word identical in two of the plaintiffs'
21 expert reports in this litigation. Is that fair?

22 MS. O'DELL:

23 Objection. Asked and answered.

24 A So reading your earlier question, you

1 asked, "Is that the same exact sentence we just
2 read in Dr. Zelikoff's report; correct?" And my
3 answer was "It is." And it remains the same.

4 Q Let's keep going.

5 Next sentence, at page 20 in
6 Dr. Zelikoff's report, states as follows:

7 "Rather," comma, "one or more additional gene
8 mutations may be needed to cause cancer."

9 Did I read that correctly?

10 A You did.

11 Q Let's go back to page 4 -- excuse me --
12 page 5 of your report where we just were. And
13 you write: "Rather," comma, "one or more
14 additional gene mutations may be needed to cause
15 cancer." Correct?

16 A Correct.

17 Q That is the identical sentence from
18 Dr. Zelikoff's report. Correct?

19 A Starting with "Rather, one or more
20 additional gene mutations may be needed to cause
21 cancer."

22 Yes, correct.

23 Q So we now have identified three
24 sentences in Dr. Zelikoff's report that are

1 identical to your report; correct?

2 A We have.

3 Q Do you have any explanation for why
4 that would be?

5 A I do.

6 Q What's that?

7 A That these -- each of these sentences
8 are describing basic introductory information
9 around the relationship between cancer and
10 genetic mutation.

11 Q And each of you described it with the
12 exact same words?

13 A Apparently so.

14 Q Let's keep going.

15 Page 20 of Dr. Zelikoff's report,
16 picking up where we left off, Dr. Zelikoff
17 writes: "The inherited gene mutation could
18 instead make one more likely to develop cancer
19 when exposed to certain cancer-causing
20 substances."

21 Do you see that?

22 A I do.

23 Q And let's go back to where we were in
24 your report, on page 5. "The inherited gene

1 mutation could instead make one more likely to
2 develop cancer when exposed to a certain
3 cancer-causing substance."

4 Do you see that?

5 A I do.

6 Q And other than the tense in that last
7 sentence, they, too, are identical. Correct?

8 A So they're -- they're certainly similar
9 sentences, but that -- I believe the tense is an
10 important difference between them.

11 Again, as I stated, that these are
12 introductory and fundamental perspectives on
13 cancer and that, in this case, two expert
14 witnesses have summarized those things in a
15 similar fashion.

16 Q It doesn't strike you as odd that four
17 sentences are identical from two expert reports?

18 MS. O'DELL:

19 Object to the form.

20 A Four sentences are not identical.

21 MS. BROWN:

22 Q There's one small change in a tense.
23 That's it. Right, Doctor?

24 MS. O'DELL:

1 Object to the form.

2 A There -- there are -- there are three
3 sentences which are, when considered
4 individually, they are the same words. When you
5 consider the -- now the group of those four
6 sentences together between the two reports, they
7 are clearly different organization with
8 significantly more information between those
9 identical sentences in one or the other.

10 So the suggestion that they were -- one
11 report was copied into the other, I would say it
12 is equally interesting that they are more
13 different than they are alike, other than the
14 wording of three sentences.

15 MS. BROWN:

16 Q Did someone other than you write the
17 sentences we've just been looking at in your
18 report?

19 A No.

20 Q Did you consult the Mayo Clinic's
21 website in connection with writing your report?

22 A I don't believe so.

23 Q Do you consider the Mayo Clinic's
24 website to be authoritative -- an authoritative

1 source, in your view?

2 MS. O'DELL:

3 Object to the form.

4 A I have no basis for that opinion. I --

5 I haven't reviewed the Mayo Clinic website to

6 determine that.

7 (DEPOSITION EXHIBIT NUMBER 9

8 WAS MARKED FOR IDENTIFICATION.)

9 MS. BROWN:

10 Q Handing you, Doctor, what we've marked

11 as Exhibit 9 to your deposition, which is a

12 printout from the Mayo Clinic website entitled

13 "Cancer."

14 A Uh-huh.

15 Q I'll hand it to you. And let me know

16 if this is something that you've ever seen

17 before.

18 A Not that I recall.

19 Q Did you take any language from the Mayo

20 Clinic website to use in your report?

21 A No.

22 Q Let's take a -- I want you to put the

23 Mayo Clinic, which we've marked as Exhibit 9 --

24 A Uh-huh.

1 Q -- next to your report, which remains
2 Exhibit 2. And I will direct you to the second
3 page of the Mayo Clinic printout, the section
4 titled "Causes."

5 Are you with me?

6 A Second page.

7 Q Double-sided. Flip it over.

8 A Yes.

9 Q Okay. And I'll direct you to page 3 of
10 your report entitled "The Role of Gene Mutations
11 in the Development of Cancer."

12 A Uh-huh.

13 Q Starting with Exhibit 9, the Mayo
14 Clinic website, under a section entitled
15 "Causes," the Mayo Clinic writes, "Cancer is
16 caused by changes" -- parentheses --
17 "(mutations) to the DNA within cells."

18 Do you see that?

19 A I do.

20 Q And, looking at page 3 of your report,
21 Doctor, that same sentence or sentence fragment
22 appears in the first sentence: "Cancer is caused
23 by changes" -- parentheses -- "(mutations) to the
24 DNA within cells."

1 Correct?

2 MS. O'DELL:

3 Object to the form.

4 A Say your question again. Are you
5 asking --

6 MS. BROWN:

7 Q It's the same; right, Doctor?

8 MS. O'DELL:

9 Object to the form.

10 A There are eight words or ten words that
11 are the same in this first sentence, again, both
12 describing some of the fundamental premise of
13 cancer and its -- in its description.

14 MS. BROWN:

15 Q Let's go to the second sentence in the
16 Mayo Clinic website, which reads, "The DNA inside
17 a cell is packaged into a large number of
18 individual genes, each of which contains a set of
19 instructions telling the cell what functions to
20 perform," comma, "as well as how to grow and
21 divide."

22 Do you see that?

23 A I do.

24 Q And a nearly identical version of that

1 sentence appears in your report at page 3 where
2 you state, "The DNA that makes up our genetic
3 code is organized into a large number of
4 individual genes, each of which contains a
5 specific subset of instructions telling the cell
6 what functions to perform," comma, "as well as
7 how to grow and divide."

8 Do you see that?

9 A I do.

10 Q Do you notice that nearly all the words
11 are the same as the Mayo Clinic's?

12 MS. O'DELL:

13 Objection to form.

14 A I, again -- we -- we have another
15 example of similar language describing
16 introductory and fundamental aspects surrounding
17 the basics of cancer biology.

18 MS. BROWN:

19 Q Back to the Mayo Clinic next sentence.

20 Quote: "Errors in the instructions can cause the
21 cell to stop its normal function and may allow a
22 cell to become cancerous."

23 Do you see that?

24 A I do.

1 Q Back to your report at page 3. An
2 identical sentence: "Errors in the instruction
3 can cause the cell to stop its normal function
4 and may allow a cell to become cancerous."

5 Do you see that?

6 A I do.

7 Q Does that strike you as strange?

8 MS. O'DELL:

9 Object to the form.

10 A Strange in what way?

11 MS. BROWN:

12 Q That your expert report in this
13 litigation contains identical sentences to the
14 Mayo Clinic's website.

15 MS. O'DELL:

16 Objection. Misstates the report.

17 A I -- I don't find it surprising in the
18 least.

19 MS. BROWN:

20 Q Let's turn to page 4 of your report,
21 please. And I'll direct you to the final bullet
22 on the same page of the Mayo Clinic website you
23 were just looking at. The section of your report
24 on page 4 I'd like to direct you to is the

1 subparagraph titled "Loss of DNA Repair."

2 Are you with me?

3 A Yes.

4 Q I'm gonna read you two sentences from
5 the Mayo Clinic. Tell me if I read them
6 correctly.

7 "DNA repair genes look for errors in a
8 cell's DNA and make corrections. A mutation in a
9 DNA repair gene may mean that other errors aren't
10 corrected, leading cells to become cancerous."

11 Do you see those two sentences, Doctor?

12 A I do.

13 Q Those are two sentences written by the
14 folks who produce the Mayo Clinic's website;
15 correct?

16 A I -- I have no knowledge of who wrote
17 that.

18 Q The same two sentences appear in your
19 report on page 4. Quote: "DNA repair genes look
20 for errors in a cell's DNA and make corrections.
21 A mutation in a DNA repair gene may mean that
22 other errors aren't corrected, leading cells to
23 become cancerous."

24 Do you see that?

1 A I do.

2 Q Those two sentences are identical in
3 the Mayo Clinic's website and your report. True?

4 MS. O'DELL:

5 Object to the form.

6 A Again, we have fund- -- basic
7 information that provides an introductory
8 description of the basics of cancer which is used
9 as -- as an inform- -- informatory foundation for
10 latter opinions in the report but is not germane
11 to the -- to the opinion in my report.

12 And, again, as stated before, that
13 succinct fundamental information regarding cancer
14 biology in two sources that state things
15 succinctly and clearly in layman's language
16 are -- are similar or even identical, again, does
17 not surprise me.

18 MS. BROWN:

19 Q We read at least four sentences that
20 are identical to the Mayo Clinic. Would you
21 agree?

22 MS. O'DELL:

23 Objection to form. The sentences are
24 not identical.

1 MS. BROWN:

2 Counsel, form.

3 A There are some similar -- there are
4 some similarly stated sentences that
5 you're -- that you've taken out of context in
6 both cases to find them identical. So I -- I
7 agree that they're identical, but, again,
8 don't -- don't necessarily am surprised since I
9 have no knowledge of where the information from
10 the Mayo website was taken from.

11 MS. BROWN:

12 Q You agree a number of sentences in your
13 report are identical to a number of sentences on
14 the Mayo Clinic's website. True?

15 MS. O'DELL:

16 Object to the form.

17 A No. I agree that they're -- I don't
18 agree. There are specific wordings that are the
19 same.

20 MS. BROWN:

21 Q Doctor, do you not agree that a number
22 of the sentences we just read are identical to a
23 number of sentences that appear on the Mayo
24 Clinic's website?

1 MS. O'DELL:

2 Object to the form.

3 A I think we've -- we've specifically
4 gone over those individually and answered those
5 questions.

6 MS. BROWN:

7 Q And you'll agree the sentences are
8 identical?

9 MS. O'DELL:

10 Object to the form.

11 A Again, I -- I've answered -- I've
12 answered those when we went through them
13 individually.

14 MS. BROWN:

15 Q Well, I want you to answer my question
16 now.

17 You'll agree we've looked at a number
18 of sentences that are identical in your report to
19 the information on the Mayo Clinic's website;
20 correct?

21 MS. O'DELL:

22 Object to the form. Misstates his
23 testimony.

24 A I'd have to go back to the transcript

1 from our conversation to comment on those.

2 MS. BROWN:

3 Q You have it right in front of you. We
4 just looked at them.

5 A We did.

6 Q Right?

7 A Yes.

8 Q You recall reading a number of
9 sentences in the Mayo Clinic website that match
10 word for word a number of sentences in your
11 report. True?

12 MS. O'DELL:

13 Object to the form.

14 A We've -- we've read information that
15 is -- that is similar between the two documents.
16 And, as answered, given the, again, basic
17 fundamental introduction in lay language for
18 these concepts, it is no surprise that it's the
19 same.

20 MS. BROWN:

21 Q You're not surprised to find identical
22 sentences in your report and Dr. Zelikoff's
23 report?

24 A I'm not surprised.

1 MS. O'DELL:

2 Object to the form.

3 MS. BROWN:

4 Q You are not surprised to find identical
5 sentences in your report and the Mayo Clinic?

6 MS. O'DELL:

7 Objection to form. Asked and answered.

8 A No. I -- I've answered that.

9 MS. BROWN:

10 Q You need to answer it again.

11 Are you --

12 A I'm not surprised.

13 Q -- surprised?

14 Did you consult Wikipedia in writing
15 your expert report?

16 A I don't recall.

17 Q Do you think it's possible you might
18 have looked at Wikipedia when writing your expert
19 report in this litigation?

20 A I've -- I've looked -- I've looked at a
21 large number of sources in published literature
22 and others.

23 Q Did one of those sources include
24 Wikipedia?

1 A I don't recall.

2 Q Do you consider Wikipedia to be a
3 scientifically reliable source?

4 A What do you mean by scientifically
5 reliable.

6 Q Do you understand the concept of
7 scientific reliability when answering a
8 scientific question?

9 MS. O'DELL:

10 Object to the form.

11 A Again, you'd have to -- that's -- you'd
12 have to explain your -- what scientific
13 reliability means in the context of your
14 question.

15 MS. BROWN:

16 Q What does it mean to you?

17 A Scientific reliability? In general
18 terms, it would mean information that comes from
19 a peer-reviewed source.

20 Q And Wikipedia is not peer-reviewed;
21 correct?

22 A Wikipedia generally reso- -- uses
23 a -- is a summary of commonly -- at least in
24 scientific terms, a number of peer-reviewed

1 sources, but it is --

2 So from a true peer-review perspective,
3 Wikipedia actually is peer-reviewed in the sense
4 that anyone can contribute and edit the
5 information in Wikipedia.

6 Q Including our kids; right?

7 MS. O'DELL:

8 Object to the form.

9 A Possible.

10 MS. BROWN:

11 Q Anyone in the world could edit a
12 Wikipedia page. True?

13 A I believe so.

14 Q Is it your testimony, Doctor, that
15 information from Wikipedia is a reliable resource
16 when answering a scientific question?

17 A No, that is not my testimony. That is
18 not my testimony, no.

19 Q Do you -- do you think you used
20 Wikipedia here in writing your report?

21 A Again, I -- I -- I don't recall using
22 Wikipedia specifically.

23 Q Okay. Let's take a look at your report
24 at page 7, Doctor.

1 And we'll mark a Wikipedia page as
2 Exhibit 10.

3 (DEPOSITION EXHIBIT NUMBER 10
4 WAS MARKED FOR IDENTIFICATION.)

5 MS. BROWN:

6 Q I would like to direct you, Dr. Levy,
7 to the first full paragraph in your expert report
8 at page 7.

9 A Uh-huh.

10 Q Do you see that?

11 A I do.

12 Q And I want to direct your attention to
13 the sentence in the middle of that paragraph that
14 begins "BRCA1 combined."

15 Do you see that?

16 A Yes.

17 MS. BROWN:

18 Q And I want to, side by side with
19 Wikipedia, direct your attention to the third
20 full paragraph that begins, as well, "BRCA1
21 combined."

22 You with me?

23 A I am.

24 Q Wikipedia writes, "BRCA1 combines with

1 other tumor suppressors, DNA damage sensors, and
2 single transducers to form a large multi-subunit
3 protein complex known as BRCA1-associated genome
4 surveillance complex" -- parens --

5 "BAC-" -- excuse me -- "(BASC)," end parens.

6 Do you see that?

7 A I do.

8 Q Turning to your report, page 7, you
9 write, "BRCA1 combines with other tumor
10 suppressors," comma, "DNA damage sensors, and
11 signal transducers to form a large multi-subunit
12 protein complex known as the BRCA1-associated
13 genome surveillance complex" -- parens --
14 (BASC)."

15 Correct?

16 A That is correct.

17 Q Those two sentences, Doctor, are
18 identical.

19 A It appears so, yes.

20 Q Okay.

21 A Except for a -- the reference included
22 on the Wikipedia page is not included in my
23 report.

24 Q Wikipedia has cited a reference, and

1 your sentence stands without a reference. Is
2 that right?

3 A That's right.

4 Q Other than the footnote, the two
5 sentences we just read are identical. True?

6 A Both sentences state the same fact in
7 the same way. So, similar to our earlier
8 discussions, we've now seen a large collection of
9 fundamental factual information with -- with
10 accurate information from now a number of sources
11 that are stated in similar ways through
12 Wikipedia, other expert reports, and websites all
13 about the fundamentals of cancer.

14 Q The two sentences we just read, Doctor,
15 are identical. Correct?

16 MS. O'DELL:

17 Object to the form.

18 A We read one sentence in Wikipedia.

19 MS. BROWN:

20 Q And it is identical. True?

21 A Yes. The wording is the same. With,
22 of course, Wikipedia, as you already stated,
23 being editable by anybody and can pull that
24 content from anywhere, and it's the -- I'd have

1 to review -- I'd have to look to see what
2 reference 16 in Wikipedia is. But it's certainly
3 possible that I and Wikipedia summarized the same
4 information from the same source.

5 Q Let's go to page 9 of your report. One
6 of the articles that you relied on is an article
7 by Lisa Coussens and Zena Werb. Do you recall
8 that?

9 A That does sound familiar, but I'll have
10 to verify.

11 Q Handing you what we've marked as
12 Exhibit 12 [sic] to your report, the Coussens and
13 Werb article.

14 (DEPOSITION EXHIBIT NUMBER 11
15 WAS MARKED FOR IDENTIFICATION.)

16 A Yes, this is a -- this is a review.
17 This is an insight review article, which, similar
18 to my report, is likely consolidating information
19 from the research knowledge.

20 MS. BROWN:

21 Q I'd like to direct you to the last two
22 sentences of Exhibit 10, the Coussens' article,
23 the last two sentences in the first paragraph.

24 A Exhibit 10 or 12?

1 Q I'm sorry. What did we mark the
2 Coussens as? 12?

3 A Twelve.

4 Q That should have been 11.

5 We have marked the Coussens' article
6 now correctly as Exhibit 11, and I'll direct you
7 to the last two sentences of the first full
8 paragraph. Put that, if you would, Doctor, side
9 by side with your report at page 9, sentence that
10 begins "in contrast," both sentences that begin
11 "in contrast."

12 Are you with me?

13 A I am.

14 Q All right. So, in this published
15 article, Ms. or Dr. Coussens writes, "In
16 contrast, proliferating cells that sustain
17 DNA" --

18 MS. O'DELL:

19 Excuse me, Alli. Sorry. Tell me, are
20 you in the second paragraph?

21 MS. BROWN:

22 I'm on the end of the first full
23 paragraph.

24 MS. O'DELL:

1 Sorry. I thought you were in the first
2 full paragraph.

3 MS. BROWN:

4 Begins "In contrast."

5 MS. O'DELL:

6 Okay.

7 MS. BROWN:

8 And we have that side by side with
9 Dr. Levy's report, page 9, the paragraph that
10 also begins "In contrast."

11 MS. O'DELL:

12 Thank you.

13 MS. BROWN:

14 Q Dr. Coussens writes, "In contrast,
15 proliferating cells that sustain DNA damage
16 and/or mutagenic assault" -- parens -- "(for
17 example, initiated cells), continue to
18 proliferate in microenvironments rich in
19 inflammatory cells and growth/survival factors
20 that support their growth."

21 Do you see that sentence?

22 A I do.

23 Q The next sentence reads, "In a sense,"
24 comma, "tumors act as wounds that fail to heal."

1 See that?

2 A I do.

3 Q Directing your attention to page 9 of
4 your report, Doctor, you write, "In contrast,"
5 comma, "proliferating cells that sustain DNA
6 damage and/or mutagenic insult -- parens -- "(for
7 example," comma, "initiated cells)," end paren,
8 "continue to proliferate in microenvironments
9 rich in inflammatory cells and growth/survival
10 factors that support their growth," period. "In
11 a sense, tumors act as wounds that fail to heal."

12 Do you see that?

13 A I do.

14 Q Except for one word, Doctor, those two
15 sentences, including the slashes and the
16 parentheses, are identical. Correct?

17 MS. O'DELL:

18 Object to the form.

19 A Those two sentences are similar.

20 MS. BROWN:

21 Q Except for one word, those two
22 sentences are identical. True?

23 MS. O'DELL:

24 Object to the form. Asked and

1 answered.

2 A Yeah. I'd certainly appreciate the
3 similarity between the -- between the two. But
4 that's -- again, as we've been discussing now for
5 an extensive amount of time, in the introductory
6 review content of the report --

7 In fact, I reference the Coussens and
8 Werb paper, so certainly it's not a surprise that
9 wording is similar between them and used similar
10 language to describe, again, these factual
11 aspects of fundamental cancer biology, including
12 similar references.

13 MS. O'DELL:

14 Excuse me. My microphone is broken.

15 VIDEOGRAPHER:

16 It's still working. You're good. You
17 can just lay it on the table and we'll fix it at
18 a break.

19 MS. O'DELL:

20 And we've been going about an hour and
21 13 minutes.

22 MS. BROWN:

23 I'm about to finish up this section.
24 We'll take a break.

1 Q My question, Doctor, was: Except for
2 one word, the two sentences we just read from
3 Coussens are identical to the two sentences in
4 your report. Is that correct?

5 MS. O'DELL:

6 Object to the form.

7 A So, I -- as -- as stated, the two
8 sentences are similar.

9 MS. BROWN:

10 Q Except for one word, they are
11 identical. Is that correct?

12 MS. O'DELL:

13 Object to the form. He's asked --
14 you've asked the question. He's answered your
15 question.

16 A Again, the two sentences are similar.

17 MS. BROWN:

18 Q Do you understand "identical," what
19 "identical" means?

20 A Yes. Exactly the same.

21 Q Okay. Except for one word, those two
22 sentences are exactly the same in the Coussens
23 article and your report. True?

24 MS. O'DELL:

1 Object to the form. Asked and
2 answered.

3 A And we're -- we're saying the same
4 thing in different ways, which is that the two
5 sentences are similar, stating factual
6 information about fundamental cancer biology and
7 in two similar review articles.

8 MS. BROWN:

9 Q And the only difference is one word.
10 Correct?

11 A Two sentences are similar.

12 Q My question was: The only difference
13 is one word. True?

14 A Let me review again to be sure that we
15 would -- before answering.

16 Taken out of context, those two
17 sentences are similar.

18 Q My question was, Doctor, the only
19 difference is one word. Is that correct?

20 MS. O'DELL:

21 Objection to the form. Asked and
22 answered.

23 A You know, I think we've -- we've
24 answered this a number of times, that the two

1 sentences are different in their context and in
2 terms of paragraph, but they are similar in
3 structure and similar in wording.

4 But, as you stated, with the exception
5 of the -- so they're not. So in a language
6 perspective, they're not identical. They're
7 similar.

8 MS. BROWN:

9 Let's take a break.

10 VIDEOGRAPHER:

11 Going off -- going off the record. The
12 time is 10:15 a.m.

13 (OFF THE RECORD.)

14 VIDEOGRAPHER:

15 We're back on the record. The time is
16 10:25 a.m.

17 MS. BROWN:

18 Q Doctor, I am handing you what I have
19 marked as Deposition Exhibit 12 and 13. These
20 are additional documents your counsel identified
21 for us this morning as something you have seen
22 since your report.

23 (DEPOSITION EXHIBITS 12 AND 13
24 WERE MARKED FOR IDENTIFICATION.)

1 MS. BROWN:

2 Q Would you tell us what those two
3 exhibits are, please.

4 A Exhibit -- Exhibit 13 is a printed copy
5 of an email dated December 26th informing
6 Dr. Saed that a manuscript --

7 Is it helpful to identify the
8 manuscript?

9 -- titled "Molecular Basis Supporting
10 the Association of Talcum Powder Use With
11 Increased Risk of Ovarian Cancer," submitted to
12 Reproductive Sciences, has been reviewed. The
13 comments were included in the letter.

14 Q Have you seen --

15 A And I'm just reading the --

16 Q Sure.

17 A It -- it appears that the -- so,
18 summarizing the letter, the manuscript has been
19 reviewed, the comments from the reviewers were
20 provided back, and the journal has informed
21 Dr. Saed that they'll accept a revised document
22 for potential publication.

23 Q Have you seen Exhibit 13 prior to this
24 morning?

1 A I have.

2 Q Have you seen the reviewer comments
3 referenced in Exhibit 13?

4 A I have not seen the reviewer comments.

5 Q Okay. Exhibit 13 does not inform the
6 opinions of your report dated November of 2018.
7 True?

8 A Exhibit 13, being the letter, that is
9 correct. It does not.

10 Q Okay. And what's Exhibit 12?

11 A Exhibit 12 appears to be a preprint
12 version of the previously mentioned paper,
13 "Molecular Basis Supporting the Association of
14 Talcum Powder Use With Increased Risk of Ovarian
15 Cancer," with the first author, Nicole Fletcher,
16 and Dr. Saed is listed as the senior or
17 corresponding author.

18 Q Did the lawyers provide you with this
19 manuscript, Doctor?

20 A Yes, in a -- but that's -- yes, they
21 did.

22 Q Do you recall when you were provided
23 with a copy of the manuscript by the plaintiffs'
24 lawyers?

1 A It was sometime in December toward --
2 late in the year. The exact date, I'd have to
3 review when it came in. And I believe it was --
4 and the version you have here is a more formal
5 preprint version from the -- from Manuscript
6 Central, whereas the version I received
7 was a -- it appeared to be more of a submission
8 version.

9 So commenting whether it's
10 exact -- precisely the same content, I -- I
11 wouldn't be able to say.

12 Q Fair to say, though, Doctor, since you
13 received the manuscript in December of 2018, the
14 contents of the manuscript did not inform the
15 expert report that you wrote in November of 2018;
16 correct?

17 A Actually, I would say the -- the -- I
18 would not agree, from the perspective of Dr. Saed
19 has a number of similar studies, as well as a
20 number of abstracts that I had the opportunity to
21 review that did inform some of the opinions in
22 the report. Those same information and data were
23 included in this manuscript and expanded upon
24 actually significantly.

1 So the basis of my opinion includes
2 some of the information from this manuscript, but
3 I -- but the report does not contain the totality
4 of this.

5 Q Right. Because the manuscript wasn't
6 available to you until after you wrote your
7 report. Right?

8 A No, that's not the case. The -- the --
9 the research, some of the research information
10 from this study was available in abstract form,
11 and -- and some -- I believe a preprint from
12 Dr. Saed.

13 So it was -- so it was available.
14 Portions of it were available for the report.

15 Q Other than the abstract, did you have
16 access to an earlier version of what we've marked
17 as Exhibit 12?

18 A I can't accurately answer that without
19 comparing them.

20 Q Where do you have stored the earlier
21 version that you're referring to?

22 A Let's see if I -- what I have here.

23 So, from Dr. Saed, I have a -- used a
24 book chapter which describes some of his

1 oxidative stress experiments that are also
2 consistent with the information that's in the --
3 in Exhibit 12, as well as some of his earlier
4 review articles, and that's --

5 Let me make sure I'm not missing
6 anything from Fletcher, who's been...

7 But, otherwise, the -- the experiments
8 that were expanded upon in the formal manuscript
9 were described in -- in abstract or, I should
10 say, summarized form, meaning an abstract that
11 included methods, results, and conclusions from
12 Fletcher and colleagues in Dr. Saed's group.

13 Q At the time you wrote your report, you
14 had an abstract of the 2018 paper that we've
15 marked as Exhibit 12; correct?

16 MS. O'DELL:

17 Object to the form. He said plural.

18 A Yes. I had two abstracts and then
19 possibly --

20 I'd have to review when I received this
21 preprint versus the final version of my report to
22 see if they overlapped, if they're -- if I had an
23 opportunity to review this or not.

24 MS. BROWN:

1 Q Okay. And I'll ask if you'd be kind
2 enough to do that at a break. Just let us know
3 if you had access to something other than the
4 abstract of Dr. Saed's 2018 report at the time
5 you wrote your report. Fair enough?

6 A I'll make a note.

7 MS. O'DELL:

8 Excuse me. Object to the form.

9 Abstracts, not one.

10 MS. BROWN:

11 Q Dr. Levy, you are a Ph.D.; is that
12 correct?

13 A Correct.

14 Q Okay. You are not an M.D.; correct?

15 A That's correct.

16 Q What's your Ph.D. in, sir?

17 A Biochemistry and genetics.

18 Q You're not an epidemiologist. Fair?

19 A I am not.

20 Q Okay. And the focus of your work at
21 HudsonAlpha is on genome sequencing. Is that
22 right?

23 A No. The -- the -- genome sequencing is
24 a tool that we apply in -- in the work of my

1 laboratory and in my responsibilities at
2 HudsonAlpha.

3 Q HudsonAlpha has a team known as the
4 Breakthrough Breast and Ovarian Cancer Team. Is
5 that right?

6 A I'm not familiar with that name.

7 Q Okay.

8 A There is a -- a group of faculty who
9 have some funding related to breast and ovarian
10 cancer. It's -- it's certainly possible that
11 name was used in -- in press for some title.

12 Q Since you're not familiar with that
13 team, fair to say you're not a member of the
14 Breakthrough Breast and Ovarian Cancer Team?

15 MS. O'DELL:

16 Object to the form.

17 A Again, I don't -- my involvement with
18 breast and ovarian cancer at HudsonAlpha is
19 specific to some projects. And whether or not I
20 was named on that team, I -- I don't know.

21 MS. BROWN:

22 Q There are folks at HudsonAlpha,
23 scientists and doctors at HudsonAlpha whose
24 practice is devoted to studying ovarian cancer.

1 Correct?

2 A No, that's not correct.

3 Q Your practice is not devoted to ovarian
4 cancer; correct?

5 MS. O'DELL:

6 Object to the form.

7 A No. My -- my practice is not devoted
8 to ovarian cancer. And -- but that was
9 irrelevant to what I was asked to do in
10 this -- in this particular case for
11 the -- regarding the content of my report.

12 MS. BROWN:

13 Q I think I saw you've published one
14 article regarding ovarian cancer over the course
15 of your career. Is that right?

16 A That sounds correct.

17 Q You have not given any presentations
18 regarding ovarian cancer. Is that true?

19 A I would say that's accurate.

20 Q You have not received any government
21 funding to study ovarian cancer. True?

22 A I received government funding to study
23 breast and ovarian cancer -- this was in 2002,
24 from the Department of Defense -- and then,

1 subsequent to that, participated in at least one
2 review for the Department of Defense in reviewing
3 ovarian cancer research grants. So that is --

4 And then my membership in the
5 Vanderbilt Cancer Center as well as the
6 University of Alabama Birmingham Comprehensive
7 Cancer Center certainly have been involved in a
8 number of projects across a diversity of cancer
9 types, including ovarian and breast cancer.

10 Q Prior to being hired by the plaintiffs'
11 lawyers in this litigation, you had not
12 investigated the potential mechanisms by which
13 talcum powder could cause ovarian cancer. Is
14 that fair?

15 MS. O'DELL:

16 Object to the form.

17 A Specific -- as in terms of a specific
18 fundamental research project?

19 MS. BROWN:

20 Q At all.

21 MS. O'DELL:

22 Object to the form.

23 A So my research has included the role of
24 inflammation and a number of biological processes

1 dating back to my early Ph.D. work, and those
2 include cancer. So certainly the subject of
3 inflammatory response in -- both chronic and
4 acute, in controlling cancer has been a subject
5 of my research for some time and certainly
6 bridged into ovarian cancer as well as other
7 cancer types.

8 MS. BROWN:

9 Q You've never published on chronic
10 inflammation as a potential mechanism by which
11 talcum powder causes ovarian cancer. Correct?

12 A Not specific to talcum powder, no.

13 Q You have never given a presentation on
14 chronic inflammation as a mechanism for causing
15 ovarian cancer at all; right?

16 MS. O'DELL:

17 Object to the form.

18 A I'm thinking through my --

19 I don't recall a specific presentation
20 with regards to talcum powder and its role in
21 ovarian cancer. As far as my discussions or
22 presentations around the role of inflammation in
23 cancer, including ovarian, it -- it is -- it is
24 possible, but I can't think of a specific

1 presentation.

2 MS. BROWN:

3 Q Okay. Since you've been hired by
4 plaintiffs' lawyers, you have done some research
5 into the potential role of inflammation and
6 ovarian cancer. Is that right?

7 MS. O'DELL:

8 Object to the form.

9 A Since -- since my -- what was requested
10 of me from the plaintiffs' attorneys was to
11 provide a review of the biological plausibility
12 and a connection between talcum powder and
13 inflammation and then discuss the relationship
14 between inflammation and cancer.

15 MS. BROWN:

16 Q Okay. As I understand you, Dr. Levy,
17 you were asked by the plaintiffs' lawyers to
18 provide a review of the literature as it relates
19 to the biological plausibility of talcum powder
20 and ovarian cancer. Is that right?

21 MS. O'DELL:

22 Object to the form.

23 A No, that's not correct. What I was --
24 I was asked to provide an opin- -- expert opinion

1 on the biological plausibility of the mechanism
2 that -- of the ability of exposure of talc and
3 its constituent components to cause inflammation
4 and/or cancer.

5 MS. BROWN:

6 Q Do you see those as two different
7 things?

8 A Yes.

9 Q Okay. So you were asked to provide a
10 mechanism by which talcum powder could cause
11 cancer?

12 A No, that's not correct.

13 MS. O'DELL:

14 Objection to form.

15 MS. BROWN:

16 Q Okay. Explain it to me.

17 A I -- I was asked to provide a -- an
18 opinion on the biological plausibility --

19 Q Of talcum powder causing cancer?

20 A -- of talcum powder leading to the
21 biological changes necessary to cause cancer.

22 Q Okay. As I understand what you just
23 said, you were asked to re- -- to provide an
24 opinion on the biological plausibility of talcum

1 powder leading to biologic changes that are
2 needed to cause cancer. Is that fair?

3 MS. O'DELL:

4 Object to the form.

5 A So I was asked from -- by the attorneys
6 to review the available literature across the
7 spectrum of cancer and talcum powder and
8 constituent literature to develop an opinion
9 around the biological plausibility that exposure
10 of -- exposure to talcum powder is
11 biologically -- that there is a biologically
12 plausible mechanism that that can cause cancer.

13 MS. BROWN:

14 Q Okay. And that is not something that
15 you had done prior to being hired by the
16 plaintiffs' lawyers. Fair?

17 A Developing such an opinion?

18 Q Correct.

19 A Or -- or -- so writing such a report,
20 no, that is not something I -- I had done prior
21 to -- to this. My research has been primarily in
22 data integration and the examination of
23 mechanistic effects in cancer, rare disease,
24 and -- and in diabetes specifically, as well as

1 some neurological diseases.

2 So this was a similar review as -- of
3 those topics when asked to examine the biological
4 plausibility of a cause and effect; in this case,
5 cause being exposure to talcum powder and effect
6 being progression to cancer.

7 Q Prior to being hired by the plaintiffs'
8 lawyers, you had not considered the biological
9 plausibility of talcum powder causing ovarian
10 cancer. Correct?

11 A No. I would say that's not true in
12 isolation. And the reason I say that's not true
13 is I had been aware of some of the literature and
14 certainly some of the press that surrounded the
15 suspected associations between talcum powder
16 exposure and cancer. So I was familiar with the
17 concept, but I had not at the time, until hired
18 by the plaintiffs' attorney, spent a significant
19 amount of time reviewing the literature and
20 developing a written opinion as to that
21 biological plausibility.

22 Q You have not published your opinion
23 contained in -- your opinions contained in the
24 report that we marked as Exhibit 2. Is that

1 correct?

2 A That is correct.

3 Q You have not presented the opinions
4 contained in Exhibit 2 at any medical or
5 scientific conference; correct?

6 A That's correct.

7 Q You have not disclosed the opinions
8 contained in Exhibit 2 to any of your colleagues;
9 correct?

10 MS. O'DELL:

11 Object to the form.

12 A Not at this time, no. Considering I
13 had -- I had just finalized the report a short
14 time ago, I haven't had the opportunity to
15 consider publication, presentation, or -- or
16 discussion with colleagues.

17 MS. BROWN:

18 Q Do you plan to seek publication of the
19 information contained in your report in Exhibit
20 2?

21 A I -- I haven't made a determination at
22 this time. It's been a fascinating area to
23 research. Certainly there's -- that would
24 certainly be a future possibility.

1 Q Does HudsonAlpha --

2 First of all, what's your position at
3 HudsonAlpha, Doctor?

4 A So I'm a faculty investigator, which
5 would be analogous to a faculty member at a
6 research institution, similar to -- or I should
7 take a step back and just --

8 To be accurate, HudsonAlpha is a
9 private nonprofit research institution, similar
10 to Broad Institute, Stowers, et cetera. So we
11 are academic in nature, meaning that most of our
12 funding or the vast majority of our funding comes
13 from grants and contracts. So that's why I say
14 it's analogous to faculty at a research
15 institution.

16 My other responsibilities are the
17 management and oversight of the production and
18 research laboratories, so that provides us an
19 opportunity to work with approximately 1200
20 different laboratories from around the world in
21 support of roughly 5,000 projects over the last
22 nine and a half years. And that's -- it's
23 provided a broad spectrum of activities and
24 abilities to work in these types of projects.

1 And then I also oversee the clinical
2 laboratories as well. And adult oncology is a
3 major focus of that research. I currently lead
4 the largest profiling effort in adult cancer in
5 the nation, which involves 15 national cancer
6 institutes. And ovarian cancer is a component of
7 that research, although not the only cancer that
8 we research in that -- in that's -- in that
9 program.

10 Q None of the 5,000 projects you just
11 mentioned have dealt with talc. Is that fair?

12 A That is fair.

13 Q And none of the work at the clinical
14 labs that you just mentioned have dealt with
15 talc; correct?

16 MS. O'DELL:

17 Object.

18 A I am -- I would say there's a
19 statistical probability that some of the ovarian
20 cancer samples that have been observed in the
21 clinical laboratory may very well have
22 been -- have come from patients exposed to talcum
23 powder. But I have no direct knowledge of that,
24 nor have we performed any testing to confirm

1 or -- or -- or dispute whether or not those
2 ovarian cancer or other cancer types may have had
3 a relationship to talcum powder. So the short
4 answer being I -- I don't have the information to
5 answer that.

6 MS. BROWN:

7 Q HudsonAlpha has a Code of Ethics. Are
8 you familiar with it?

9 A Yes.

10 Q Are you familiar with the financial
11 disclosure requirements of HudsonAlpha?

12 A I am.

13 Q Have you complied with those in
14 connection with your work as an expert witness
15 for plaintiffs in this case?

16 A I have.

17 Q And tell us what you've done to comply
18 with HudsonAlpha's Code of Ethics and financial
19 disclosure requirements.

20 A Their Code of Ethics and financial
21 requirement is requirement to disclose any
22 relationships that have a financial component
23 over -- I don't recall the minimum amount, but it
24 is -- it is fairly modest, hundreds of dollars.

1 And that reporting requirement is the -- is -- is
2 for the previous year, and it is due in July, I
3 believe is the time frame, although I'd have to
4 make sure. It's -- I know it's not the end of
5 the calendar year. So on my next disclosure,
6 this, of course, activity would be disclosed.

7 In addition to that, via
8 conversation -- regular review with the president
9 of the institution, I provide a general report on
10 consulting activities; for example, these
11 activities.

12 HudsonAlpha's policy is faculty members
13 are allowed up to 20 percent of your time towards
14 consulting activities that have a relationship to
15 your research area, such as the evaluation of the
16 biologically plausible mechanism of talc in
17 ovarian cancer. So based on both the timing of
18 the Code of Ethics with regards to the financial
19 disclosure as well as the ad hoc reporting of
20 consulting engagements with the president of the
21 institution, I'm in compliance with the current
22 policies of HudsonAlpha.

23 Q The president of HudsonAlpha is aware
24 of your opinions in this case?

1 A I have not discussed my opinions
2 specifically to this case with him; just the
3 general knowledge that I was asked to participate
4 as an expert witness. He didn't ask, and I
5 didn't provide the content.

6 Q No one at HudsonAlpha is aware of your
7 opinion that talcum powder causes chronic
8 inflammation which can cause ovarian cancer? Is
9 that right?

10 A I have -- I have not specifically
11 shared the contents of the report or -- or my
12 opinions widely at HudsonAlpha.

13 Q Did you disclose last July that you had
14 already been hired and submitted invoices to the
15 plaintiffs' lawyers?

16 A I'm sure I did.

17 Q Do you have that documentation?

18 A No. It's -- it's an electronic
19 disclosure. It's not actually done on paper.

20 Q One of the things that HudsonAlpha does
21 is it partners with the University of Alabama in
22 a comprehensive cancer center; correct?

23 A No, that wouldn't be correct.
24 HudsonAlpha is very specific --

1 And you may be more familiar with this
2 than I.

3 They're very specific with their use of
4 the word "partnership" and they're, in fact, very
5 specific that they do not engage in a -- anything
6 titled "a partnership." So they -- I would not
7 characterize them as a partner of the University
8 of Alabama Cancer Center.

9 We certainly have -- there are faculty
10 members at University of Alabama Birmingham who
11 are -- have adjunct appointments at HudsonAlpha,
12 just as I have appointments at University of
13 Alabama Birmingham and I am a member of their
14 cancer center.

15 Q Are you aware of the work that
16 HudsonAlpha does with the University of Alabama's
17 Comprehensive Cancer Center?

18 MS. O'DELL:

19 Object to the form. Asked and
20 answered.

21 A I'm aware of some of the work, but I --
22 certainly I -- I don't -- I don't necessarily
23 have knowledge of the full spectrum of those
24 projects, given that they involve many faculty

1 members on both institutions.

2 MS. BROWN:

3 Q Fair to say, then, Doctor, you have not
4 participated in any work with the University of
5 Alabama's Comprehensive Cancer Center?

6 MS. O'DELL:

7 Object to the form.

8 A No, that's not true.

9 MS. BROWN:

10 Q Have you worked with the University of
11 Alabama's Comprehensive Cancer Center on projects
12 involving ovarian cancer?

13 MS. O'DELL:

14 Objection. Asked and answered.

15 A I would -- I would have to review the
16 specific projects that we've -- we've done to
17 answer that.

18 As the codirector of a core facility
19 for the University of Alabama Comprehensive
20 Cancer Center, it is likely that we've worked on
21 some projects related to ovarian cancer, but I
22 can't specifically name them. They are -- I
23 would -- I would characterize them as infrequent.

24 MS. BROWN:

1 Q Have any of those projects attempted to
2 research the potential causes of ovarian cancer?

3 A Again, I'd have -- I'd have to review
4 the projects. They're certainly --
5 fundamentally, most of the questions regarding
6 the analysis of cancer samples are routinely to
7 investigate their cause or their treatment. So I
8 would -- I would answer that question as highly
9 likely.

10 Q Would you agree the cause of ovarian
11 cancer remains unknown today?

12 MS. O'DELL:

13 Object to the form.

14 A No, I would -- I would -- I would not
15 agree that it -- I would not agree to that
16 general statement.

17 MS. BROWN:

18 Q What are the causes of ovarian cancer
19 in your mind, Doctor?

20 A Well, the -- the causes of -- of
21 a -- of any number of cancers, including ovarian
22 cancer, are probably more well understood now
23 than ever, and their complexities I think now are
24 just beginning to be appreciated in the sense

1 that cancer is a disease of unregulated cell
2 growth.

3 Back to our earlier con- -- earlier
4 conversation, some of the fundamental facts that
5 we had discussed and, in fact, I think well
6 replicated in a number of sources, as you pointed
7 out to me, you know, illustrate that there's a
8 milieu of genetic change leading to cellular
9 transformation, and that cellular damage, if we
10 consolidate that as cellular damage, then has to
11 work in concert with a number of other events
12 providing the right environment for a tumor to
13 grow, such as inflammation, chronic or acute.
14 And, so, the -- you know, the -- the -- you know,
15 giving a singular cause would be inappropriate.

16 But I would say the mechanistic causes
17 of cancer are reasonably well understood, but how
18 those apply to the wide diversity of cancer types
19 remains an area of active investigation.

20 I think what's interesting on cancer in
21 general is that there's no -- really no longer a
22 bucket diagnosis. It is -- it -- lung cancer is
23 more complex than lung cancer and ovarian cancer,
24 certainly with the --

1 As I'm sure you're well aware, with the
2 molecular subtypes and other things, it's a
3 complicated disease as well.

4 So to summarize that is -- to summarize
5 all of that complexity by saying that the cause
6 is known or unknown I think would vastly
7 underestimate the -- our current state of the art
8 or knowledge of how complex cancer is as a
9 condition.

10 Q Sure.

11 Scientists, researchers, public health
12 authorities continue to investigate the mechanism
13 by which ovarian cancer is caused. Correct?

14 A That's correct.

15 Q We do not, sitting here today in 2019,
16 have a complete understanding of the etiology of
17 ovarian cancer. Correct?

18 MS. O'DELL:

19 Object to the form.

20 A I would say we have substantial
21 knowledge of factors and exposures that either
22 predispose or directly cause cancer in a large
23 number of -- large number of cancer areas,
24 including ovarian cancer.

1 Now, the -- whether that represents the
2 complete milieu of possibilities is -- is what is
3 currently under research.

4 MS. BROWN:

5 Q Were you aware that the University of
6 Alabama Comprehensive Cancer Center is an NCI
7 center, National Cancer Institute?

8 A Yes. It's -- it's not only an
9 NCI-designated center; it's an NCI-designated
10 comprehensive cancer center, which is a slightly
11 different classification. It's a -- there's more
12 criteria for a cancer center to meet to become
13 comprehensive.

14 Q What does it mean to be an NCI center,
15 to you, if you know?

16 A Stated very simply, it means you have
17 a -- your cancer center is funded by a support
18 grant directly from the National Cancer Institute
19 to provide -- that supports not only patient care
20 but also supports basic research, epidemiology
21 and -- and health outcomes research in cancer.

22 So, in a nutshell, it is a fairly
23 comprehensive grant that supports a wide variety
24 of work within a cancer center that extends

1 beyond basic -- basic care.

2 Q The National Cancer Institute has
3 funded a number of projects that the scientists
4 at HudsonAlpha are working on. Is that fair?

5 A I'd have to certainly review the grant
6 portfolio. But I'm certain that, since I myself
7 have funding from that cancer center, yes, the
8 NCI does fund some -- some number of
9 investigators at HudsonAlpha.

10 Q And you consider the NCI to be a
11 reputable public health authority; correct?

12 A No, not necessarily. The NCI is really
13 not a public health authority. The N -- the NCI
14 is a -- is a scientific administration center
15 within the National Institutes of Health.

16 Now, I'm speaking of their extramural
17 programs. The NCI also have intramural programs,
18 where they have their own researchers and their
19 own projects. I'm less familiar with those
20 activities.

21 But together, I would state that the
22 NCI is a -- I don't have -- I guess I have not
23 had any experience with the NCI that would lead
24 me to say that they are an authoritative public

1 health authority.

2 Q Before forming your opinions in this
3 case, Dr. Levy, did you look to see what the NCI
4 states about whether talcum powder causes ovarian
5 cancer?

6 A I believe I did see, from a number of
7 statements, certainly potentially from the NCI,
8 regarding the complete opinion and -- and
9 knowledge base for the role of talcum powder in
10 ovarian cancer.

11 Q Do you recall that the NCI has
12 concluded that there's inadequate evidence that
13 talcum powder increases the risk of ovarian
14 cancer?

15 MS. O'DELL:

16 Object to the form.

17 A Which -- what specifically are you
18 referring to? I -- I wouldn't be able to answer
19 that accurately without knowing which specific
20 report or statement that you're referring to.

21 MS. BROWN:

22 Q I'm wondering if, sitting here today,
23 you recall looking at information about the
24 classification of risk factors for ovarian cancer

1 as done by the NCI.

2 A I don't recall that specifically. I
3 don't also recall seeing any statements from the
4 NCI regarding safety of any product.

5 Q In forming your opinions in this case,
6 Dr. Levy, did you consider the conclusions of
7 public health authorities like the FDA, the NCI,
8 NIH as it relates to talcum powder in ovarian
9 cancer?

10 A So I certainly considered information
11 from each of those entities. But I would make a
12 statement I don't -- I don't recall from any of
13 those entities seeing a single conclusion.

14 Q Is it your opinion, Dr. Levy, that
15 talcum powder causes ovarian cancer?

16 A I wasn't asked to provide an opinion if
17 talcum powder causes cancer. I was -- I was
18 asked to develop an opinion as to the biological
19 plausibility of -- of talcum powder leading
20 to -- leading to change.

21 Now, that's what I was asked from the
22 attorneys. If you're asking -- are you asking me
23 what my opinion is --

24 Q Well, I want to know if, in this case,

1 you are prepared to offer the opinion that talcum
2 powder causes ovarian cancer.

3 A I don't -- I don't think we have the
4 complete information for a sing- -- you know, to
5 have the opinion of a singular cause. But, at
6 the same time, my opinions are that, as stated in
7 the report, there's a clear and well-evidenced
8 biologically plausible role for talcum powder
9 leading to ovarian cancer.

10 Q On page 2 of your report, the second
11 full paragraph that begins "My report
12 consists" --

13 You with me?

14 A Yes.

15 Q -- you state -- you reference your
16 conclusions regarding this cause-and-effect
17 relationship.

18 Do you see that?

19 A I do.

20 Q Do you mean by that that you have an
21 opinion that talcum powder causes the effect of
22 ovarian cancer?

23 A No. That -- that wasn't the meaning of
24 that statement of cause and effect. It was -- it

1 was a -- more of a general statement of a cause
2 being exposure to talc and effect being that
3 biologically plausible mechanism.

4 Q You mentioned a moment ago that you
5 don't think we have the complete info on a
6 singular cause of ovarian cancer. Is that right?

7 MS. O'DELL:

8 Objection to form.

9 A Sorry. Let me read your question
10 again.

11 I have -- I have not seen any evidence
12 that suggests that there is a singular cause of
13 ovarian cancer.

14 MS. BROWN:

15 Q You have not seen sufficient evidence
16 to suggest that talcum powder could be one of the
17 causes of ovarian cancer; correct?

18 MS. O'DELL:

19 Object to the form.

20 A I would disagree. As -- as stated,
21 the -- I have not seen evidence that there's a
22 singular cause of ovarian cancer. I think there
23 is ample evidence that there are a multitude of
24 mechanisms that you can get cellular damage and

1 cellular change within the ovary which then leads
2 to malignant transformation, and that, as stated
3 in the report, there's a biologically plausible
4 mechanism that exposure to talcum powder and its
5 constituents can create those necessary changes.

6 MS. BROWN:

7 Q Do you believe, Doctor, there's
8 sufficient evidence that talcum powder, through
9 chronic inflammation, causes ovarian cancer in
10 some individuals?

11 A No. That -- that was not my -- not my
12 opinion or statement. And I would say
13 specifically chronic inflammation is, again,
14 narrowing the focus in an inappropriate way, and
15 the evidence doesn't illustrate that chronic
16 inflammation is a singular sufficient detail or,
17 I should say, effect to result in ovarian cancer.
18 It's certainly a factor, as -- as well described
19 in the -- in the literature.

20 And -- and, again, I would defer to
21 other expert reports that have similar opinions
22 regarding inflammation, chronic inflammation
23 being one of them.

24 And it may be important to provide an

1 important distinction that cellular damage or
2 what we can refer to as acute inflammation can
3 cause -- certainly has been shown and is
4 well-evidenced that it causes -- can lead to
5 molecular changes that can lead to cancer.

6 Chronic inflammation is a slightly --
7 is in a slightly different biological perspective
8 in that it provides the correct environment for
9 those cancerous changes to take hold and allow
10 malignant transformation, as I mentioned.

11 So I -- I do view them as working in
12 concert but not necessarily independent. So when
13 you ask a question that specifically narrows it
14 to chronic inflammation or even acute
15 inflammation in a singular fashion, you know, my
16 answers will largely be the same, that that's, in
17 and of itself, is too limited to describe as a
18 specific cause, singular or otherwise, of ovarian
19 cancer or of cancer in general.

20 Q You'd agree that the research regarding
21 whether chronic inflammation can cause ovarian
22 cancer is ongoing?

23 A Yes, I would agree it is -- it is
24 ongoing research. But there are a large number

1 of observations and studies that
2 have -- certainly exist. And, again, their
3 review and -- and content is what went to the
4 opinions in my report.

5 Q And most of the studies that you cite,
6 Dr. Levy, talking about chronic inflammation
7 refer to chronic inflammation as a hypothesis of
8 one of the ways cancer might form in the ovary.
9 Correct?

10 MS. O'DELL:

11 Object to the form.

12 A Let me -- sorry. Let me read your
13 question.

14 No. I would disagree. At least,
15 certainly not most of the studies that I cite.

16 MS. BROWN:

17 Q Do you believe chronic inflammation is
18 an established mechanism of ovarian cancer?

19 A Yes, in the sense that chronic
20 inflammation is a well-established mechanism of
21 cancer in general, including ovarian cancer.
22 This is first observed in the 1800s and has since
23 been -- become well-established in the -- in the
24 cancer field that inflammation plays a

1 significant role in both the initiation as well
2 as progression of cancer.

3 Q What methodology did you employ for
4 coming to the opinion that chronic inflammation
5 is a well-established cause of ovarian cancer?

6 A Just general mechanism in terms of
7 evaluating biological plausibility.

8 Q I understand, Dr. Levy, you have a
9 general opinion that chronic inflammation can
10 lead to some cancer. Is that right?

11 MS. O'DELL:

12 Objection to form. Misstates his
13 testimony.

14 A I -- I have an opinion regarding the
15 role and importance of inflammation in the
16 initiation and progression of cancer.

17 MS. BROWN:

18 Q And, as it relates to ovarian cancer,
19 what methodology did you employ to arrive at your
20 conclusion that chronic inflammation is an
21 established cause of ovarian cancer?

22 A I -- I did not arrive at that specific
23 conclusion, nor was I asked to.

24 Q You do not believe that chronic

1 inflammation has been established as a cause of
2 ovarian cancer; correct?

3 MS. O'DELL:

4 Object to the form.

5 A No, that -- that's not what I said.

6 MS. BROWN:

7 Q Explain it to me.

8 A I've stated that chronic inflammation
9 or inflammation in general, including chronic and
10 acute infor -- inflammation, is a component and a
11 necessary component for the initiation and
12 progression of -- of cancer as we understand it
13 today. And, in that, cancer, certainly ovarian
14 cancer as well as a variety of other cancer
15 types, is included.

16 Q What methodology did you employ to
17 arrive at the conclusion that ovarian cancer is
18 one of the cancers that can be caused by chronic
19 inflammation?

20 MS. O'DELL:

21 Object to the form. Misstates his
22 testimony.

23 A Yeah. Again, we're not -- I'm not
24 making a specific causal opinion with respect to

1 any -- whether -- whether inflammation, talcum
2 powder use or other exposures. I -- my -- my
3 opinion in the report is -- is -- was not asked
4 to be a causal opinion.

5 MS. BROWN:

6 Q You reference on page 2 of your report
7 that your opinions are based on assessing and
8 weighing the totality of the evidence, including
9 relevant literature and available documentation
10 and your experience as a geneticist and
11 scientific researcher. Do you see that?

12 A Yes.

13 Q What do you mean by "the totality of
14 the evidence"?

15 A All of the evidence available at the
16 time that I was researching this report.

17 Q All of the evidence concerning what?

18 A Concerning a variety of subjects
19 surrounding ovarian cancer, talcum powder use,
20 and then inflammation and related subjects as my
21 literature review and review of available
22 information progressed.

23 So there was a, I guess, a large number
24 of tangential directions that -- that I examined,

1 from animal models to in vitro studies, in vivo
2 studies, cohort studies, case-control studies.
3 There was quite a broad spectrum of information
4 across a large number of years.

5 Q Do you believe you reviewed the
6 totality of the epidemiology on talcum powder use
7 and ovarian cancer?

8 MS. O'DELL:

9 Object to the form.

10 A I -- I reviewed the available studies
11 that appeared to be relevant for the -- for the
12 opinions that are expressed in my report.

13 MS. BROWN:

14 Q And when you say "available," what do
15 you mean?

16 A Meaning that I could -- I could
17 discover in the scientific literature.

18 Q Did you conduct your own literature
19 searches in connection with your work in this
20 case?

21 A I did.

22 Q How did you go about finding the
23 totality of the evidence relating to whether
24 talcum powder causes ovarian cancer?

1 A So the -- my methodology for the
2 literature review in establishing my opinion
3 regarding the biological plausibility of talcum
4 powder exposure inflammation and its potential
5 role in ovarian cancer was based on, you know, my
6 activities and many other literature searches, so
7 using a variety of computational tools and -- and
8 web-based resources, from journals to, I would
9 say, primarily PubMed being a resource, but also
10 ISI, Web of Science, Google Scholar and a variety
11 of -- bioRxiv and I'm sure a number of other
12 sources. But those were probably the more
13 primary resources for establishing what
14 literature was available.

15 Q Did you ask the plaintiffs' lawyers for
16 any scientific literature that you used in
17 forming your opinions in this case?

18 A What do you mean by "ask"? There
19 is -- as far as did I ask for their similar
20 process, no.

21 There were some papers that I had
22 identified but was not able to access the full
23 content via the libraries that I have access to.
24 So in some of those cases, specific references

1 that I provided, those full -- that full content
2 was provided by the plaintiffs' lawyer to allow
3 me to review it.

4 Q Did the plaintiffs' lawyers give you a
5 set of epidemiology on which you're relying on to
6 form your opinion?

7 A No, they did not.

8 Q If I look at your report, I see a
9 reference list and then a separate Exhibit B. Is
10 that right?

11 A Yes.

12 Q So, for example, on page 18 of your
13 report, you have a list of literature cited.
14 Correct?

15 A Yes.

16 Let me make sure I have the page
17 correct.

18 Yes, beginning on page 18.

19 Q Is everything that appears in the
20 literature-cited list something that you found on
21 your own, Dr. Levy?

22 A I would have to review the -- the list.
23 But there are certainly --

24 Let me --

1 I believe the Saed abstracts, as an
2 example --

3 Let me see if there are --

4 No. I -- I believe, in the literature
5 cited, there are certainly some number of
6 examples of information that was provided during
7 the course of the development of my report from
8 the plaintiffs' attorneys in terms of literature
9 for my consideration, but that in no case -- in
10 every case it was provided as a -- as
11 information.

12 The vast majority or nearly the
13 totality of this was information that I had --
14 that I indeed discovered myself and shared with
15 the -- the attorneys, but certainly not complete.

16 Q On page 18 you cite an article by
17 Blount.

18 Do you see that?

19 A Yes.

20 Q Was that given to you by the
21 plaintiffs' lawyers?

22 A I'd have to look at my records. I
23 don't recall.

24 Q Off of the top of your head, are you

1 relying on information in that article to form
2 your opinions in this case?

3 A No. I'm not relying on any singular
4 article or source to form my opinion on the case.

5 Q Are you relying in part on the
6 information contained in the Blount article?

7 A Since I include it in the cited
8 literature, certainly in some -- in some part.

9 Q What information are you relying on in
10 the Blount article?

11 A I would have to review the article to
12 remind myself where the --

13 Q Take a look at it. We'll pull it right
14 now.

15 What about Paoletti on page 22? Was
16 that something you found on your own or did the
17 lawyers give you that?

18 A So Paoletti --

19 Q Uh-huh.

20 A Page 22?

21 Q Uh-huh.

22 A Actually, the Paoletti one is familiar.
23 That's an interesting one because it's in
24 Italian.

1 Q Are you relying on the information in
2 the Paoletti article to form your opinions in the
3 case?

4 A Again, the -- I wasn't relying on any
5 singular article but instead tried to present and
6 provide reference to as comprehensive a
7 collection of relevant literature in this -- in
8 this space as possible, of which Paoletti,
9 although being in Italian, there were some --
10 enough translated aspects of that that it was
11 worthy to include in the -- in that cited
12 literature as being relevant to the -- to
13 those -- to those opinions.

14 Q Just to make sure we get on the same
15 page here, Dr. Levy, when I ask are you relying
16 on something, I don't mean by that question to
17 suggest it's the only thing you're relying on.
18 And I'll try to say "in part" to make it easy for
19 us. Okay?

20 A Right. Just want to be -- make sure
21 we're clear.

22 Q Absolutely. So do I.

23 And I want to know are you relying in
24 part on anything in the Paoletti article to form

1 your opinions in this case?

2 A I would say in -- in part. As far as
3 my opinions regarding the biologically plausible
4 mechanism that was presented, no, it does not
5 rely on that specific conclusions of that paper
6 but, rather, that paper was included because of
7 its results regarding asbestos contamination in
8 industrial talc, which only support -- add
9 support to the mechanism that I presented in the
10 report.

11 Q Is your opinion in this case, Doctor,
12 based on an assumption that baby powder contains
13 asbestos?

14 A No, it is not.

15 MS. O'DELL:

16 Object to the form.

17 MS. BROWN:

18 Q Is your opinion in this case based on
19 an assumption that baby powder contains
20 fragrances?

21 MS. O'DELL:

22 Objection to form.

23 A My -- my opinion considers the totality
24 of the constituent components of baby powder,

1 Shower to Shower, you know, under -- either, as
2 we've been referring to it simply as talc or
3 talcum powder or by trade names such as
4 Johnson & Johnson or Shower to Shower, so the --
5 my opinions, as stated in the report, being
6 reasonably -- or trying to be reasonably
7 comprehensive. Therefore, it's not, you know,
8 limited to any -- any singular component, whether
9 it be majority or minority, in the -- in the
10 talcum powder products, as I just stated.

11 MS. BROWN:

12 Q Is your opinion in this case based on
13 an assumption that Johnson & Johnson baby powder
14 products contain heavy metals?

15 MS. O'DELL:

16 Objection to form.

17 A Again, similar to the earlier
18 statement, the opinion is not subject to
19 any -- any singular component. I think the
20 information regarding the -- in deferring to some
21 of the other experts regarding the knowledge of
22 constituent components, whether they be heavy
23 metals or asbestos, only helps to support the
24 biological plausibility of the mechanism I

1 presented.

2 MS. BROWN:

3 Q Do you believe that baby talc alone can
4 cause inflammation that may lead to ovarian
5 cancer?

6 A Based on my review of the literature,
7 there are a number of studies, both of those
8 involving human studies in terms of case
9 controls, as well as a number of animal studies
10 and then, more specifically, in vitro studies
11 that look at talcum powder and its ability to
12 produce clear markers of inflammation.

13 I am -- the -- I am not aware of any
14 specific testing that looked at platy talc
15 individually as a singular component without
16 the -- or out of the context of the products we
17 were just describing in a similar analysis. So I
18 don't -- I don't know that answer.

19 Q Is it your opinion that
20 Johnson & Johnson baby powder products are
21 contaminated with asbestos?

22 MS. O'DELL:

23 Object to the form. Asked and
24 answered.

1 A I -- I -- I have -- I have been
2 provided expert report, and some of those are
3 referenced in the -- in the report, as we were
4 describing, that describe testing of a number
5 of -- number of samples,
6 included -- Johnson & Johnson included in that,
7 that showed how they -- that the results of those
8 reports showed contamination by asbestos or --
9 or -- or asbestos-like fiber. So, therefore,
10 I've been presented with that evidence.

11 MS. BROWN:

12 Q Have you relied on that evidence in
13 forming your opinions in this case?

14 A Again, no, not -- not as a singular
15 evidence. So, as we just discussed a moment ago,
16 that is a component piece of evidence that
17 leads -- and is supportive of the biologically
18 plausible mechanism described in the report.

19 You know, certainly, it is inarguable
20 that asbestos and asbestos-like fibers cause
21 inflammation. There's also ample evidence of the
22 inflammatory effects of talc. And -- and talc
23 pleurodesis, for example, is -- is designed to
24 produce inflammatory response as a treatment.

1 So I think, again, similar to the
2 relationship of asbestos and inflammation, it's a
3 well-established scientific fact that talc has an
4 inflammatory role now. Or I should say as of
5 today.

6 Q Have you attempted to quantify, based
7 on the reports of Dr. Longo that you reviewed,
8 how much asbestos contamination is in
9 Johnson & Johnson baby powder products?

10 MS. O'DELL:

11 Objection. Vague as to form.

12 A I --

13 MS. O'DELL:

14 As to the volume and time contained,
15 et cetera.

16 A My -- my answer is simply that I wasn't
17 asked to quantify that as part of my report.

18 MS. BROWN:

19 Q Whether there is asbestos in Johnson &
20 Johnson baby powder products or not does not
21 impact your opinions in this case; is that right?

22 MS. O'DELL:

23 Object to the form.

24 A The opinions regarding the biological

1 plausibility described in my report and its
2 relationship to asbestos are somewhat separate,
3 meaning that I have -- I was not able to discover
4 what the contamination rate or content of
5 asbestos was in any of the referenced studies
6 through the course of my report, so, therefore, I
7 can't comment on the likelihood or -- of -- of
8 how many or any -- or any or all of those samples
9 contain asbestos.

10 MS. BROWN:

11 Q And sounds like you did some work
12 attempting to see if you could calculate a
13 contamination rate. Is that what you were
14 describing?

15 MS. O'DELL:

16 Object -- object to the form.
17 Misstates his testimony.

18 A No. No, not at all. I stated that I
19 didn't have information available to assess
20 either -- either way.

21 MS. BROWN:

22 Q Tell me what you meant when you
23 testified that you were not able to discover what
24 the contamination rate or content of asbestos was

1 in any of the above-referenced studies.

2 MS. O'DELL:

3 Objection. Misstates his testimony.

4 A So reading -- reading back my

5 testimony --

6 MS. BROWN:

7 Q So, Doctor, I see that you're looking
8 at the realtime?

9 A Yes.

10 Q To get clarification on the question?

11 A No. To -- to remem- -- to -- you asked
12 me a question about my statement.

13 Q Correct.

14 A And I was reviewing specifically what I
15 had stated so I could answer your question
16 accurately.

17 Q Terrific. So I want to know what you
18 were talking about when you said you were unable
19 to discover the contamination rate.

20 A To clarify, I was not asked to estimate
21 or determine the contamination rate, and my
22 statement regarding that was in reference to the
23 material I reviewed and the literature that is
24 referenced in my report. I don't recall in any

1 of those studies observing a specific statement
2 of amount of asbestos in the talcum powder
3 products that were under study. So, therefore, I
4 am not able to form an opinion surrounding that
5 contamination rate.

6 Q Would the same be true, Doctor, for
7 heavy metals?

8 A Yes, that's correct.

9 Q And when I say the same would be true,
10 that means you were not able to calculate a rate
11 of heavy metal contamination of any of the talcum
12 powder products in the studies you reviewed?

13 MS. O'DELL:

14 Objection. Vague.

15 A I was not asked to.

16 MS. BROWN:

17 Q Did you attempt to quantify the amount
18 of heavy metals?

19 MS. O'DELL:

20 Objection.

21 A I certainly reviewed the literature to
22 understand what information was available
23 regarding the products that may have been used
24 and what testing may have been done on

1 those -- on those products.

2 MS. BROWN:

3 Q And, as it relates to fragrances, have
4 you calculated the amount of fragrances that are
5 present in Johnson & Johnson's baby powder
6 products?

7 MS. O'DELL:

8 Objection to form.

9 A I -- I wasn't asked to -- to make those
10 calculations. And I would defer to other expert
11 reports that I had an opportunity to review
12 recently that did perform those calculations.

13 MS. BROWN:

14 Q Your opinions in this case are not
15 dependent on whether or not --

16 A I think that was --

17 Q -- there are fragrances in
18 Johnson & Johnson's baby powder; correct?

19 MS. O'DELL:

20 Objection.

21 A Sorry. Let me read that.

22 Sorry. Could you rephrase your
23 question? The question that appears on the
24 monitor is that there are fragrances in

1 Johnson & Johnson baby powder, question mark.

2 MS. BROWN:

3 Q That's why it's tricky when you read
4 the realtime. Just listen to my question. It'll
5 be more helpful.

6 Your opinion in this case is not
7 dependent on whether or not there are fragrances
8 in Johnson & Johnson baby powder. Correct?

9 MS. O'DELL:

10 Excuse me. Objection to form.

11 You may refer to realtime any time you
12 want to, Doctor.

13 But I object to the form of the
14 question.

15 A So my -- my -- I was -- what was
16 requested of me, again, stating for clarity, was
17 to describe a biologically plausible mechanism
18 for talc and all of its constituent components
19 having a role in inflammation and progression to
20 ovarian cancer based on -- on the information at
21 hand.

22 Certainly the fact, as we've been
23 provided later, the ex- -- the recent review of
24 some other expert reports regarding the

1 fragrances as well as asbestos, I would say my
2 opinion now is that that information continues to
3 support the biologically plausible mechanism
4 presented in my report.

5 MS. BROWN:

6 Q Your opinion that chronic inflammation
7 is a biologically plausible mechanism by which
8 talcum powder could cause ovarian cancer is not
9 dependent on heavy metals being present in talcum
10 powder; correct?

11 MS. O'DELL:

12 Object to the form. Asked and
13 answered.

14 A My -- my opinions are not based on --
15 on any singular component or constituent because
16 the -- the available information did not
17 scientifically test any singular components
18 or -- or allow --

19 I'm not aware of any studies that
20 examine the inflammatory or other effects of
21 talcum powder that contained heavy metals versus
22 did not.

23 MS. BROWN:

24 Q So, for purposes of your opinions in

1 this case, for your piece of the puzzle, so to
2 speak, it is not important to you whether or not
3 there are heavy metals in baby powder; correct?

4 MS. O'DELL:

5 Objection to form. Asked and answered.

6 A No, that's not correct. I would say
7 the presence of all of the constituent components
8 is very important for -- from the -- from the
9 perspective of that biologically plausible
10 mechanism, and that includes the type of talc,
11 the structure of the talc, you know, its -- any
12 potential contaminants that are there, as well as
13 the complete spectrum of other constituent
14 components, fragrances, heavy metals.

15 And, of course, fragrances have their
16 own milieu of constituent components that, again,
17 I was not asked to comment on or describe in
18 detail but certainly are part of the overall
19 studies.

20 MS. BROWN:

21 Q You have a conclusion in your report on
22 page 17, Doctor, conclusion number 2, that talcum
23 powder products cause chronic inflammation.

24 Do you see that?

1 A Yes.

2 And I would -- and then my conclu- --

3 Q Hold on. No question yet.

4 A Okay.

5 Q And what I want to know, Doctor, is how
6 do you define the talcum powder products that
7 you've listed here on page 17 of your report?

8 A Primarily the products that are -- when
9 I consider the totality of everything that I've
10 been examining, the talcum powder products,
11 including Johnson & Johnson and Shower to Shower
12 as, you know, I refer to those consumer products
13 under the term "talcum powder."

14 Q What about other consumer talcum powder
15 products? Are they included in your conclusions
16 here on page 17?

17 MS. O'DELL:

18 Object to the form.

19 A So my -- my conclusions are based on
20 the -- on the literature review. And, similar to
21 our discussions regarding contaminants and the
22 ability to quantitate those, many of the studies
23 did not specifically delineate which product or
24 the timing of that product.

1 In contrast, some of the more recent
2 information available specific to the
3 constituents did meet that definition, so I would
4 say these conclusions apply to both the specific
5 products that I mentioned, Johnson & Johnson and
6 Shower to Shower, as well as potentially other
7 products. But quant- -- quantifying which study,
8 I would have to go through study by study to
9 answer any questions about which specific may be
10 included.

11 MS. BROWN:

12 Q Do you include talc-containing
13 deodorizing sprays in your definition of a talcum
14 powder product?

15 A None of the literature that -- that I
16 reviewed or can recall was limited to those
17 deodorant sprays in terms of a -- as a study
18 variable that I can -- that I can think of.

19 Q I'm not sure what you mean by that.

20 A So the -- the basis of this report was
21 on the talcum powder products, and I don't recall
22 any of the studies that delineated talcum powder
23 as a powder versus a talc-containing deodorant
24 spray as a -- as a variable in the study. So I

1 don't know if any of the studies used -- used
2 that. I'd have to, again, would have to review
3 some of that information to determine if there
4 was a -- if that was a variable in any of the
5 given studies that are the basis of the report.

6 Q What methodology did you employ here in
7 coming to your conclusion that chronic
8 inflammation is caused by talcum powder products?

9 MS. O'DELL:

10 Objection. Asked and answered.

11 A Yeah. Again, to restate, similar to
12 the earlier questions, the -- my methodology was
13 based on standard methodology for establishing
14 biological plausibility, which is a, in a
15 summary, a review of the totality of the evidence
16 and then a summary of that to establish if, based
17 on established or -- or known or factual
18 principles, is there a -- can -- can a mechanism
19 described go from cause to effect in a -- again,
20 in an evidence-supported biologically plausible
21 manner.

22 There's a few references I can provide
23 you that describe that method in a published
24 manner, if that's helpful.

1 MS. BROWN:

2 Q That would be helpful.

3 A They are -- these are our --

4 MS. O'DELL:

5 These are mine.

6 THE WITNESS:

7 Yeah.

8 There's a -- I can get them --

9 MS. BROWN:

10 Q Are the published methods referenced in
11 your report, Doctor?

12 A No, actually, those are not.

13 Q Okay. How would you go about finding
14 the published methods that contain a description
15 of the methodology you employed in this case?

16 A No. It's that I was just saying that
17 there's a published -- peer-reviewed published
18 article that is the same as the method I used, if
19 you -- if you wanted to review that. I didn't
20 reference this specific paper in the report.

21 Q Okay. And you have a -- do you have a
22 copy of that in front of you right now, Doctor?

23 A I do.

24 Q Okay. So let's mark that as Exhibit

1 14.

2 (DEPOSITION EXHIBIT NUMBER 14
3 WAS MARKED FOR IDENTIFICATION.)

4 MS. BROWN:

5 Q The title of the document is
6 "Evaluating Biological Plausibility in Supporting
7 Evidence For Action Through Systematic Reviews in
8 Public Health."

9 When is the first time you reviewed
10 this document, Doctor?

11 A In the last -- the last day or so.

12 Q Was the document provided to you by the
13 lawyers for plaintiffs?

14 A Yes.

15 Q The document is not referenced in your
16 report. True?

17 A It is not referenced. That's correct.

18 Q You did not review the document prior
19 to writing your report; correct?

20 A That's right.

21 Q The document was something the lawyers
22 for plaintiffs gave you after you had already
23 written and authored your report; correct?

24 A That's correct. I provided that as an

1 example of the -- of a published example of the
2 methodology that I employed.

3 Q You didn't endeavor to research the
4 scientific literature to find a published --
5 published example of your methodology, did you?

6 MS. O'DELL:

7 Objection to form.

8 A I -- it wasn't -- that wasn't what I
9 was -- I wasn't asked to reference the
10 methodology in my report. I was, again, asked to
11 provide an opinion on a biologically plausible
12 mechanism and then, since our discussion has
13 transferred to methodology, to be complete, I
14 wanted to provide an example of a published
15 version of the methodology that -- that is
16 similar to or at least describes in a summary or
17 really in that particular paper an exemplary
18 fashion of the criteria for biological
19 plausibility and the methods used therein.

20 MS. BROWN:

21 Q Exhibit 14 is the product of research
22 the lawyers for plaintiffs conducted on a
23 published article regarding your methodology.
24 True?

1 MS. O'DELL:

2 Object to the form.

3 A No, that's not true.

4 MS. BROWN:

5 Q The lawyers for plaintiffs found
6 Exhibit 14 in the scientific literature; correct?

7 A That's correct.

8 Q In reviewing the scientific literature,
9 did you pay attention to the articles that
10 classify different types of talcum powder
11 products?

12 MS. O'DELL:

13 Object to the form.

14 A Could you give a specific example, and
15 then I --

16 I wouldn't be able to answer without
17 knowing.

18 MS. O'DELL:

19 Q Sure.

20 Do you understand that some of the talc
21 epidemiology separates use by type of talcum
22 powder product?

23 MS. O'DELL:

24 Objection to form.

1 A Again, do you have a specific example
2 of one of the studies so I could -- so I'd be
3 able to accurately answer your question?

4 MS. BROWN:

5 Q Here's what I want to know. Did you
6 look at the studies that separated deodorizing
7 sprays from powder products from cornstarch, for
8 example?

9 A Certainly in my review I made as
10 comprehensive a review of available literature
11 as -- as possible. And, again, if you can name a
12 specific study or one of the references, I can
13 confirm if that was -- if that was part of
14 the -- my review of the epidemiology.

15 Q Do you hold the opinion that talcum
16 powder-containing deodorant sprays causes
17 inflammation?

18 MS. O'DELL:

19 Objection to form. Vague.

20 A So if the --

21 Again, I was asked to provide an
22 opinion on the biologically plausible mechanism
23 regarding talc and talcum powder. So,
24 presumably, any product that contains talcum

1 powder could possibly follow that same
2 biologically plausible mechanism.

3 MS. BROWN:

4 Q Is there a certain amount of talcum
5 powder that a product must contain to cause
6 inflammation?

7 MS. O'DELL:

8 Objection to form.

9 A That wasn't something I was asked
10 to -- to quantify, similar to the discussions we
11 had about metals, fragrances, and asbestos.

12 MS. BROWN:

13 Q In forming your opinion that talcum
14 powder products cause inflammation, you have not
15 attempted to quantify how much talcum powder is
16 in those products; is that right?

17 MS. O'DELL:

18 Objection to form. Asked and answered.

19 A So my -- my review included a number of
20 studies that looked at exposure rates, and my
21 review also included the review of some studies
22 that did not include use frequency as well as use
23 duration. And, so, both of those considerations
24 in terms of my review of the epidemiology were

1 undertaken, but I did not attempt to quantify
2 those relationships specifically.

3 MS. BROWN:

4 Q Okay. So there's two different issues
5 there that I want to ask you about. One, I want
6 to talk to you about whether the talcum powder
7 products you've described on page 17 of your
8 report have a specific composition, in your mind.
9 Okay?

10 Two, I want to talk to you about what
11 you were just answering, which is is there a
12 specific amount of the product that you believe
13 causes inflammation.

14 Do you understand the difference?

15 A I do.

16 MS. O'DELL:

17 Objection to form.

18 MS. BROWN:

19 Q Okay. So let's start, one, with the
20 product. In forming the opinion that talcum
21 powder products cause inflammation, is there a
22 particular chemical composition that you are
23 relying on?

24 MS. O'DELL:

1 Objection to form. Vague.

2 A My -- my opinions are based on the
3 available scientific literature regarding the
4 testing performed on talcum powder and talcum
5 powder products.

6 I -- in my review of those results, I
7 did not see a specific enumeration of any one
8 particular chemical composition that was -- had a
9 greater or lesser cause or effect relationship.

10 MS. BROWN:

11 Q Do you know how much talcum powder is
12 in the Shower to Shower product?

13 A No. I wasn't -- I wasn't asked to
14 quantify that, and I would defer to some of the
15 other expert reports regarding the composition of
16 those products.

17 Q Do you include cornstarch as a talcum
18 powder product?

19 MS. O'DELL:

20 Object to the form.

21 A Cornstarch was included in some of the
22 epidemiology studies, as you -- as you mentioned
23 a moment ago.

24 MS. BROWN:

1 Q Do you consider cornstarch to be a
2 talcum powder product that also causes
3 inflammation?

4 MS. O'DELL:

5 Object to the form.

6 A My -- my review of the literature
7 doesn't -- I'm thinking through the available
8 studies, and I don't recall which studies that
9 may -- may have been a dependent variable in
10 terms of the determination. So I -- I can't
11 answer that. I -- I don't have the information
12 to answer that accurately.

13 MS. BROWN:

14 Q So, sitting here today, you're not sure
15 if cornstarch would be a talcum powder product
16 that causes inflammation as you described on page
17 17?

18 MS. O'DELL:

19 Objection.

20 A No. So --

21 MS. O'DELL:

22 Misstates the testimony.

23 But you may answer if you understand
24 the question.

1 A So corn -- cornstarch and -- and talcum
2 powder are -- are -- when I'm referring to talcum
3 powder and talcum powder products, cornstarch, as
4 a singular component -- or singular product, is
5 not included in that definition.

6 Now, whether products that contain talc
7 also contain cornstarch, I -- I'm not able to
8 say.

9 MS. BROWN:

10 Q Right. And so that's my question.
11 What about a product like Shower to Shower that
12 contains talc and cornstarch? How have
13 you -- what methodology have you employed to
14 arrive at the conclusion that the Shower to
15 Shower product causes inflammation?

16 MS. O'DELL:

17 Object to the form.

18 A So my -- what I was requested was to
19 write an opinion as to the, again, the
20 biologically plausible mechanism that exposure to
21 talc and its constituents can lead to
22 inflammation.

23 I wasn't asked to provide as to what
24 the minimum or maximum thresholds are of any

1 product or of any component of that product or
2 constituent.

3 The information I was provided was the
4 analysis of products like Shower to Shower and
5 Johnson & Johnson's product, to evaluate the
6 spectrum of talc and asbestos contamination in
7 some of the constituent components, and then --
8 and, therefore, develop an opinion as to
9 the -- whether or not that those products are
10 supported by the same mechanism that I developed
11 the opinion on, meaning they have the constituent
12 components to cause inflammation.

13 MS. BROWN:

14 Q You have not made a determination of a
15 particular amount of talcum powder that is
16 required to be in a product for it to cause
17 chronic inflammation; correct?

18 MS. O'DELL:

19 Object to the form.

20 A I wasn't asked to provide such an
21 opinion.

22 MS. BROWN:

23 Q Your opinion that talcum powder
24 products cause chronic inflammation is not based

1 on knowledge of how much talcum powder is
2 actually in the product; correct?

3 MS. O'DELL:

4 Objection. Misstates his testimony.

5 A Again, not a -- it wasn't part of -- it
6 wasn't an opinion I was asked to provide.

7 The -- the only -- or, I should say,
8 a -- a study that looked at the -- summarizing
9 the epidemiology literature that I reviewed, some
10 of those studies had a duration and component as
11 far as general talcum powder and talcum powder
12 product use.

13 MS. BROWN:

14 Q And I want to --

15 A I don't --

16 MS. O'DELL:

17 Excuse me. Let him finish.

18 A I was -- I was going to say I don't
19 recall those quantitating the percentage of
20 talcum powder in a -- in a given product in the
21 study.

22 MS. BROWN:

23 Q Right. And, so, you're getting a
24 little into the second question, which I do want

1 to talk about, which is how much people are
2 exposed to.

3 But sticking with just what's in the
4 product, have you made a determination that there
5 is a threshold amount of talcum powder that is
6 required to be in a product before you can
7 conclude that that product will cause chronic
8 inflammation?

9 MS. O'DELL:

10 Objection to form. Asked and answered.

11 A I -- again, I wasn't asked to provide
12 that -- that threshold opinion.

13 MS. BROWN:

14 Q And understanding whether or not there
15 is a threshold of how much talcum powder has to
16 be in a product to cause inflammation is not
17 necessary for you to opine that talcum powder
18 products cause chronic inflammation?

19 MS. O'DELL:

20 Objection. Misstates his testimony.

21 A So my -- my use of the terminology
22 "talcum powder products" includes the product and
23 all of its constituent components, which would
24 be, as we earlier discussed, talcum powder,

1 fragrances, and any contaminating substances,
2 such as asbestos or -- or heavy metals.

3 And, so, therefore, to -- to more -- to
4 answer -- to be able to answer your question
5 accurately, we would -- I think we would have to
6 have some discussions as to the type of talcum
7 powder and the level of exposure to be able to
8 answer that regarding my opinion in terms of
9 level.

10 You know, the -- to clarify, the --
11 during this research and the -- and having the
12 opportunity to review much of the literature in
13 talcum powder, it's a -- it's a fascinating field
14 because it is similar to asbestos. It appears
15 that the diversity of products and the diversity
16 of talc sources are like having a thorn bush with
17 different size thorns, and, depending on the
18 constituent components, you know, those thorns
19 are bigger or smaller or otherwise. And -- but
20 my opinion is based on the fact that the presence
21 of any of those thorns is sufficient to cause
22 some inflammatory response.

23 MS. BROWN:

24 Q Does a talcum powder product with 10

1 percent talc cause chronic inflammation, in your
2 view?

3 MS. O'DELL:

4 Object to the form. Incomplete
5 hypothetical.

6 A I -- I don't have the information to
7 answer that.

8 MS. BROWN:

9 Q Does a talcum powder product with
10 50 percent talc cause chronic inflammation, in
11 your view?

12 A Again, I don't have the information to
13 answer that.

14 MS. O'DELL:

15 Object to the form.

16 MS. BROWN:

17 Q Is it necessary for you to determine
18 the level of talc in a product before determining
19 that it can cause chronic inflammation?

20 MS. O'DELL:

21 Objection. Asked and answered.

22 A No. My -- my -- so my opinion was
23 asked to answer the question of can -- is there a
24 biologically plausible mechanism from talc

1 exposure to inflammation to the initiation of
2 core progression of cancer. And that's -- that's
3 been the focus of my opinion.

4 MS. BROWN:

5 Q Have you attempted to quantify talc
6 exposure as it relates to individuals?

7 A No, I have not.

8 Again, my -- my opinions are primarily
9 limited to the -- to the biological mechanism.

10 Q Well, isn't that dependent, though, on
11 how much talc a person is exposed to?

12 MS. O'DELL:

13 Objection.

14 A No. Again, separating the -- so the
15 question of the mechanism is --

16 Can an exposure result in a mechanism
17 is separate from how much of an exposure is
18 required to cause that mechanism.

19 MS. BROWN:

20 Q So you've identified two questions for
21 us. One, can exposure result in a mechanism.
22 Correct?

23 A (Nods affirmatively.)

24 Q And, two, how much of an exposure do

1 you need to produce a mechanism. Correct?

2 MS. O'DELL:

3 Objection to form.

4 A Correct.

5 MS. BROWN:

6 Q And, in this case, you have answered
7 question number one, can exposure to talc cause
8 chronic inflammation. Correct?

9 A So my -- yeah. My -- my report details
10 the -- that opinion regarding a biologically
11 plausible mechanism.

12 Q You have not, in this case, answered
13 question number two, which is how much exposure
14 to talc is needed to cause chronic inflammation.
15 Is that right?

16 MS. O'DELL:

17 Objection to form.

18 A I wasn't asked to provide such a
19 mechanism or such a -- such an opinion.

20 Part of my review included some of the
21 epidemiology studies that examine that question,
22 but I certainly would defer to the -- the number
23 of -- of epidemiologists who are -- who are
24 providing testimony in this case, rather than try

1 and paraphrase or opine on their work.

2 MS. BROWN:

3 Q Do you believe --

4 MS. O'DELL:

5 Excuse me. We've been going about an
6 hour and 15 minutes. I'd love to take a break in
7 the next two or three minutes and --

8 MS. BROWN:

9 It will probably take me a little
10 longer than that, but I'm mindful of the time,
11 and I'll just finish this subject and take a
12 break --

13 MS. O'DELL:

14 Well, Dr. Levy, would you like a break
15 now?

16 THE WITNESS:

17 I think we can finish this subject.

18 MS. BROWN:

19 Thank you.

20 THE WITNESS:

21 I -- I'd rather conclude it than break
22 it up.

23 MS. BROWN:

24 Q So, Doctor, as it relates to how much

1 talc is needed to cause inflammation that can
2 cause cancer, that wasn't what you were asked to
3 figure out in this case. Is that right?

4 MS. O'DELL:

5 Objection to form.

6 A No. Well, I -- I was -- I was asked to
7 provide a review of the literature in terms of
8 talc exposure and inflammation and, in that
9 review, identified a number of studies that
10 examined some relationships to dose.

11 But I -- as you -- as you see in my
12 conclusions, none of them speak to dose or
13 duration in terms of that -- of that mechanism.

14 MS. BROWN:

15 Q You are not offering an opinion in this
16 case, Doctor, that perineal use of talcum powder
17 exposes an individual to enough talc to cause
18 chronic inflammation than can cause cancer;
19 correct?

20 MS. O'DELL:

21 Objection to form.

22 A My review of studies that attempted to
23 answer that specific question found a -- or a
24 number of studies, both -- or a number of

1 epidemiology studies found that conclusion and,
2 as -- as reviewed in the report, you know, found
3 an increased risk with increasing -- increasing
4 exposure appears, with the current knowledge in
5 the literature, to increase risk. But my opinion
6 was not to further quantify or further describe
7 that.

8 MS. BROWN:

9 Q Many of the studies you looked at did
10 not show a dose response; correct?

11 MS. O'DELL:

12 Objection to form.

13 A The limitation of several of the
14 studies I reviewed was that they did not examine
15 a dose response, so that, therefore, the study
16 was unable -- unable to make that conclusion
17 because they didn't look.

18 MS. BROWN:

19 Q And some of the studies that did
20 attempt to look at duration and/or frequency did
21 not show a linear dose response. Correct?

22 A I would have to look at the specific
23 studies. But in -- in summary, studies that did
24 look at dose response, particularly more recent

1 studies with larger numbers of participants, the
2 meta-analysis studies, found a significant
3 relationship between duration of use as well as
4 frequency of use in terms of their -- their risk
5 ratios.

6 Q And you are not going to offer the
7 opinion in this case that a woman using Johnson's
8 Baby Powder products perineally is exposed to
9 enough talcum powder to cause chronic
10 inflammation that can cause cancer. True?

11 MS. O'DELL:

12 Object to the form.

13 A I -- I wasn't asked to -- to provide
14 that opinion.

15 MS. BROWN:

16 Q And so, as such, you haven't attempted
17 to quantify how much talcum powder, as used
18 perineally, might get to the ovary. Is that
19 fair?

20 A Again, wasn't -- wasn't asked. I was
21 able to review some of the literature that
22 is -- appears to be long -- longstanding, well
23 established over the last greater than 40 years
24 that show a clear -- and I believe the FDA

1 statement is -- is describing it as inarguable --
2 that talc can migrate either from perineal
3 exposure or even from inhalation exposure and be
4 found in the ovary.

5 A quantitation of how much exposure is
6 required for that migration to occur and -- or
7 how many times of exposure that migration needs
8 to occur, I think it's been a fairly wide
9 diversity of -- of studies on that subject.

10 And, so, based on that, I'm not able to
11 offer an opinion as to a minimal or maximum dose
12 required to get there, other than -- but,
13 instead, state that there is enough evidence to
14 say factually that migration through the -- or
15 through at least two mechanisms of exposure, talc
16 can be found in the ovary. And I would suggest
17 that -- or I'm not aware of any study that
18 quantitates that further.

19 Q Is it essential to your opinion that
20 talc causes chronic inflammation that can lead to
21 ovarian cancer that some amount of talc be
22 present in the actual ovary?

23 MS. O'DELL:

24 Object to the form.

1 A So my -- my -- my opinion regarding the
2 biologically plausible mechanism, again, does not
3 rely on duration of exposure or amount of
4 exposure.

5 So, therefore, I would -- I would
6 answer your question directly that it would be
7 no, it does not -- it would not necessarily
8 require talc to be present at the ovary at any
9 given time point for there to be the potential
10 that she had some inflammatory injury due to talc
11 exposure at a previous time.

12 That would, of course, be two different
13 questions, one being effect of exposure and
14 second question being is there clearance of that
15 exposure over time if use is discontinued.

16 So that's, again, two different -- two
17 very different scientific studies would be --
18 would be necessary.

19 MS. BROWN:

20 Q And you have not undertaken either of
21 those studies. Is that fair?

22 A That's fair.

23 Q And -- but essential to your theory,
24 though, Doctor, at some point, some amount of

1 talc has to reach the ovary for the chronic
2 inflammation to occur. Is that right?

3 MS. O'DELL:

4 Objection.

5 A Not -- specific to your question,
6 chronic inflammation, no, not necessarily.

7 MS. BROWN:

8 Q Is it your opinion in this case,
9 Doctor, that a woman can develop ovarian cancer
10 from chronic inflammation from talc without any
11 particle of talc ever reaching the ovary?

12 MS. O'DELL:

13 Objection to form.

14 A No, I didn't -- I -- I certainly did
15 not make that statement. And the --

16 Again, restating the -- this summary of
17 my -- my opinion, that the biologically plausible
18 mechanism for talc exposure to inflammation to
19 cellular damage and then potentially creating the
20 correct environment is based on evidence showing
21 talc exposure in the ovary.

22 MS. BROWN:

23 Q Okay. So critical to your opinion,
24 then, some talc has to get to the ovary at some

1 time; right?

2 A Well, the -- again, the -- my opinion
3 is not based on how talc migrates or -- or when
4 it can migrate. It's simply based on the, again,
5 that biological premise, that exposure to talc.

6 So I wasn't asked to opine whether or
7 not talc exposure in a neighboring tissue could
8 cause enough of an inflammatory response to
9 affect the ovary.

10 So there is the, certainly, the
11 uninvestigated secondary effects that perhaps
12 talc did not -- is not necessary or -- and
13 required to get to the ovary to cause that
14 effect. I'm -- I'm just not aware of any studies
15 that have made that delineation of talc exposure
16 to neighboring or surrounding organs.

17 There is limited or some suggestion
18 regarding the inflammatory response related to
19 talc exposure in the lung that suggests that any
20 talc exposure causes an inflammatory response.
21 Again, but I can't point you to evidence that
22 would take that inflammatory response and tie it
23 specifically to ovarian cancer.

24 So, again, my answer is there is not

1 enough evidence to -- to support nor refute that
2 any talc exposure can lead to an increased risk
3 of ovarian cancer. What I do know from my review
4 of the literature is the studies that looked at
5 that specific exposure --

6 And, to be clear, none of the
7 epidemiology studies in humans quantitated the
8 amount of talc reaching the ovary. It was simply
9 the exposure and the -- and the perineal use of
10 talc. So I think any discussion about how much
11 did it reach the ovary and how long was it in the
12 ovary is all hypothetical.

13 Q Why don't we go off the record and take
14 a break.

15 Thank you, Doctor.

16 VIDEOGRAPHER:

17 Going off the record. The time is
18 11:51 a.m.

19 (LUNCH RECESS.)

20 VIDEOGRAPHER:

21 We're back on the record. The time is
22 12:52 p.m.

23 MS. BROWN:

24 Q Welcome back, Doctor.

1 You were asked in this case to assess
2 whether perineal use of talcum powder products
3 induces a biologically plausible mechanism or
4 mechanisms that result in ovarian cancer.

5 Correct?

6 A Correct.

7 Q And define for us, if you will,
8 "biologically plausible mechanism" as you used it
9 in that sentence.

10 A Excuse me. A mechanism that is
11 biologically plausible, I mean that it is
12 supported by either well-established biological
13 facts or supported by at least a single line of
14 evidence in published literature -- you know,
15 generally speaking, peer-reviewed literature but
16 certainly not limited to that -- where when you
17 take -- when you consider the totality of the
18 mechanism, that, essentially, each of the steps
19 makes sense and is -- is supported by -- through
20 either direct or indirect observations.

21 Q Okay. And, in this case, as it relates
22 to talcum powder, do you believe that the
23 biologically plausible mechanism of chronic
24 inflammation causing ovarian cancer is supported

1 by well-established biological facts?

2 A I would say the -- that chronic
3 inflammation as a component of causing ovarian
4 cancer is well established by biologically
5 plausible facts.

6 Q And what are those facts?

7 A I think a number of studies that
8 include the, first, the -- that talc or talcum
9 powder causes inflammation. These exist in a
10 number of forms, including very recent -- recent
11 research by Dr. Saed, as we were -- touched on a
12 little bit earlier in the -- in his paper, as
13 well as classical studies with talc pleurodesis
14 where there's -- you know, the fundamentals of
15 that treatment is the inflammatory response
16 caused by talc.

17 Q Uh-huh.

18 A And, so, that would be the -- some of
19 the -- two examples of where factual information
20 or at least observations that are supportive
21 of -- of that information, you know, being
22 considered as a bio- -- part of a biologically
23 plausible mechanism.

24 Q You would agree, Doctor, that not all

1 inflammation causes cancer; correct?

2 A I would say inflammation is not
3 singularly responsible for cancer. However, I
4 would clarify that the progression from cellular
5 transformation to malignant cancer, at least with
6 our current understanding of cancer biology,
7 appears to have an inflammatory requirement,
8 meaning that all cases of chronic inflammation
9 don't necessarily cause cancer. However, our
10 understanding of malignant transformation appears
11 to have, universally, an inflammatory component.

12 Q Okay. You would agree, though, that
13 not all types of inflammation that the body
14 experiences is inflammation that will lead to
15 cancer. Correct?

16 MS. O'DELL:

17 Object to the form.

18 A So I would -- taking a step back
19 and -- and -- or to orient us to some of the
20 basis of my opinions and some statements on
21 general cancer biology --

22 MS. BROWN:

23 Q Well, let's start with just the
24 question, though, Doctor.

1 A Okay.

2 Q Okay. Let's just keep it to an answer
3 to the question. And then if you need an
4 opportunity to make another statement on the
5 record, that's fine.

6 MS. O'DELL:

7 Excuse me. Just object to the
8 direction of the witness.

9 Dr. Levy, you can answer a question
10 however you'd like.

11 MS. BROWN:

12 Q And, just to orient you, Doctor, what
13 I'm after, the question was: Not all
14 inflammation that takes place in the body is
15 inflammation that leads to cancer; correct?

16 MS. O'DELL:

17 Object to the form.

18 A So that, yeah, it's really too general
19 a question. So you're -- you're -- what you're
20 asking is does all inflammation have the
21 potential to have -- have a relationship to
22 cancer, and the answer to that is -- is yes, it
23 does.

24 Now, does every inflammatory response

1 directly cause cancer? And that's a question
2 that I would say would be reasonable to -- in
3 layperson's terms, in terms of general
4 inflammation, is unlikely.

5 But there -- their distinction
6 between -- is -- you know, stated simply, is
7 inflammation is a -- by our current knowledge of
8 cancer, is a necessary component of cancer
9 progression. That does not equate to all
10 inflammation causing cancer.

11 MS. BROWN:

12 Q Does acute inflammation cause cancer,
13 in your mind, Doctor?

14 A It is a component of the cancer
15 progression process. And, so, in my -- to
16 provide a simplistic distinction between them is
17 a --

18 Acute inflammation which results in
19 either an inflammatory response or direct
20 cellular insult or injury can be viewed as having
21 a -- causing cellular damage that results
22 in -- in cellular transformation.

23 Now, that is not sufficient for that --
24 for those transformed cells to then go on to

1 cause cancer. The -- you need a contribution of
2 other factors. And what those factors are is --
3 some are understood. Some are areas of active
4 research.

5 In the -- in the specific case of
6 ovarian cancer, it does appear, given the
7 late- -- given the observations about latency
8 period, that some level of chronic inflammation
9 appears to be critical, but there is no
10 definition of it being required to then having
11 acute inflammation, again, in summary, causing
12 cellular damage and then chronic inflammation
13 providing a -- a supportive environment for that
14 transformation.

15 And, again, I'm -- I'm generalizing,
16 which, as we discussed earlier in the day, cancer
17 is very complex, and so we have to be cautious
18 with generalizations.

19 Q Talc pleurodesis is a medical procedure
20 by which talc is injected into the pleura;
21 correct?

22 A Correct.

23 Q And it is done that purposefully to
24 elicit an inflammatory response. Correct?

1 A That's correct.

2 Q And have you looked in consid- --
3 forming your opinions in this case at the body of
4 epidemiology that has followed folks who received
5 talc pleurodesis to see if they developed cancer?

6 MS. O'DELL:

7 Object.

8 A Somewhat, yes.

9 MS. BROWN:

10 Q And are you familiar with the findings
11 of those studies that talc, when injected
12 directly into the pleura for the purpose of
13 causing inflammation, had not caused cancer?

14 MS. O'DELL:

15 Object to the form.

16 A I would disagree with your conclusions.
17 And, in fact, the literature I reviewed has, I
18 think, two fundamental concerns. One is the time
19 period that these patients were followed post
20 pleurodesis, and the other that there -- there
21 have been at least one report, perhaps two -- I
22 would have to review to make sure I'm speaking
23 accurately -- where there was indeed a
24 asbestos-like response in the formation of a

1 mesothelioma-like event in the -- in the -- in
2 the pleural space following talc pleurodesis.

3 However, you know, taking a step back,
4 given the relative rarity of that as a procedure,
5 particularly today, I think drawing conclusions
6 from that as its -- as its relationship to cancer
7 would be difficult, but I -- I do think
8 fundamentally the -- my use of that as an example
9 was not necessarily to tie talc specifically to
10 cancer. It was more to state that it's well
11 established that platy talc individually as it --
12 used in those procedures causes an inflammatory
13 response. And so, you know -- and that is the
14 primary reason I used or reviewed that literature
15 for that purpose.

16 MS. BROWN:

17 Q Is it your opinion, Doctor, that talc
18 pleurodesis leads to cancer?

19 MS. O'DELL:

20 Object to the form.

21 A It is my opinion that talc pleurodesis
22 creates an environment supportive of cancer. And
23 whether or not some number of individuals may
24 progress, could progress or have progressed to

1 cancer is -- you know, is -- is of limited
2 knowledge right now.

3 MS. BROWN:

4 Q What scientific support do you have for
5 your opinion that talc pleurodesis creates an
6 environment supportive of cancer?

7 A Oh, just that it causes an inflammatory
8 response. And, as we've been discussing, there
9 is ample evidence surrounding the role of
10 inflammation in cancer. There's a -- you know,
11 in a number of both reference studies and I think
12 generally, I would -- I would state that it's a
13 generally accepted fact in cancer biology.

14 Q What scientific support do you have for
15 your opinion that talc pleurodesis patients later
16 can and do develop cancer?

17 MS. O'DELL:

18 Object to the form. Misstate his
19 testimony.

20 A I'd have to review my -- review some of
21 the literature. And I can take a look if we want
22 to pause for a moment.

23 But there was -- I recall one study
24 involving talc pleurodesis that was maybe

1 mid-'80s to early '90s. I'd have to, again, have
2 to review that --

3 I gave that specific example of a
4 patient or cohort of patients that were found to
5 have, again, asbestos-like effects in the lung
6 leading to, at least in a case or more than
7 perhaps more than one case, a mesothelioma-like
8 effect like we -- like I just mentioned.

9 But, again, to point you to the exact
10 reference, I'd have to review.

11 MS. BROWN:

12 Q Are you relying on that reference in
13 forming your opinions in this case?

14 A No. Specifically -- again, to restate
15 the -- my description of the pleurodesis process
16 was to support the early part of the biological
17 mechanism that talc causes inflammation. So
18 that -- and, so, in the lung as a tissue, that
19 progression to cancer is -- is -- I think is a --
20 is a -- is a supportive observation to the -- to
21 my overall principle. But, again, it's a
22 separate -- separate exposure type, certainly a
23 very different dosing, potentially, and, again, a
24 very different patient, or the patient is a very

1 different individual in the sense that they
2 obviously have reasons for going through the talc
3 pleurodesis which are -- which are -- which are
4 potentially compounding to the overall phenotype.

5 Q Have you endeavored to quantify the
6 difference between exposure to talc from
7 pleurodesis versus perineal use of cosmetic
8 talcum powder products?

9 MS. O'DELL:

10 Object to the form.

11 A I have -- I have not attempted to
12 delineate those two simply from the perspective
13 that, again, to the biological mechanism, the
14 initial premise is talc causes inflammation. And
15 when I examined literature to look for evidence
16 of that historically, talc pleurodesis is one
17 example of inflammation. There's now others, and
18 there's, subsequent to that, there's been
19 a -- now a number of -- or, you know, probably
20 a --

21 Dr. Saed is one example of a reasonably
22 comprehensive molecular study examining specific
23 inflammatory markers tied specifically to
24 cellular exposure to, in the case of that paper,

1 specific products, you know, such as the Shower
2 to Shower and the -- and baby powder.

3 MS. BROWN:

4 Q Do you believe the inflammation caused
5 by talc pleurodesis is chronic inflammation that
6 leads to cancer?

7 MS. O'DELL:

8 Objection to form. Asked and answered.

9 A Again, I believe the inflammatory
10 response to talc exposure, which would include
11 talc pleurodesis, induces an inflammatory
12 response that would be supportive of cancer
13 development and/or progression.

14 MS. BROWN:

15 Q And what scientific literature other
16 than the one study you just referenced for us do
17 you rely on for your opinion that talc
18 pleurodesis induces an inflammatory response that
19 would be supportive of cancer development and/or
20 progression?

21 MS. O'DELL:

22 Object to the form.

23 A All my -- my opinion is based on
24 connecting two basic concepts. Talc exposure

1 causes inflammation. Inflammation has a
2 significant role in cancer development.

3 And, so, as far as -- each of those is
4 supported by individual -- individual studies,
5 and -- and now -- as I mentioned, there are now
6 studies that directly tie those together in
7 observation.

8 MS. BROWN:

9 Q What is the scientific basis for your
10 support that talc exposure causes the type of
11 inflammation that has been linked to cancer?

12 A The most recent is the Saed publication
13 that we discussed and -- or at least has been
14 mentioned. In that study, looking at -- there
15 was a assessment and, in some cases, a
16 quantitation of the specific molecular markers
17 for inflammation that were induced, and many
18 of -- some of those markers are shared with known
19 markers for -- for cancer progression, such as
20 CA 125, as well as others.

21 Q Are you referring to Saed's 2018 paper,
22 Dr. Levy?

23 A Yes.

24 Q And you formed the opinions that talcum

1 powder products cause chronic inflammation in
2 your November 2018 report before having seen the
3 Saed paper from 2018; correct?

4 MS. O'DELL:

5 Object -- object to the form.
6 Misstates his testimony.

7 A The -- so, as we discussed -- we
8 discussed earlier, I had seen abstract
9 information as well as earlier publication from
10 Dr. Saed's group and that the current 2018 paper,
11 while not necessary for the opinions described in
12 the report, certainly support those opinions,
13 given that it was a direct assessment of specific
14 products, specific -- in specific doses applied
15 to cellular material and then measurements for
16 inflammation made directly on that material.

17 So while that particular study was
18 not --

19 And, again, the -- the earlier studies
20 that were used to inform the 2018 paper were
21 certainly used in this report and referenced
22 the --

23 And I'm just recalling when. Or if
24 we've refer- -- had the opportunity to reference

1 the --

2 Yeah. So we reference primarily the
3 abstracts and then, again, as well as some of the
4 other Saed work, which is the foundation of the
5 directed studies that are described in the
6 Reproductive Sciences paper that is Exhibit 12.

7 MS. BROWN:

8 Q Do you know that Dr. Saed is a paid
9 expert for the plaintiffs' lawyers in this
10 litigation?

11 A I am aware. Yes.

12 Q Have you considered that fact in
13 evaluating Dr. Saed's work?

14 A I did.

15 Q Other than Dr. Saed's work from 2017
16 and 2018, what evidence are you relying on to
17 support your opinion that talcum powder produces
18 the type of inflammation that can lead to cancer?

19 A There has been -- looking through
20 the -- there's the Buz'Zard and Lau, 2007. We
21 were discussing the Hamilton -- Hamilton paper in
22 terms of immune response but then, more
23 specifically, the NTP reference in 1993. And in
24 those cases, that was either looking at increases

1 in reactive oxygen species generation --

2 THE COURT REPORTER:

3 Wait a minute. You have to slow down
4 when you read, please.

5 MS. O'DELL:

6 You may continue.

7 A Just to -- before I left off, I think,
8 in those mentioned references, the reactive
9 oxygen species generation, increased cell
10 proliferation, and the use of -- in the specific
11 case of Buz'Zard and Lau, was looking at the
12 transformation in human ovarian cancer cells that
13 were treated with talcum powder -- sorry -- human
14 ovarian cells treated with talcum powder.

15 MS. BROWN:

16 Q Other than Buz'Zard, Hamilton, and NTP,
17 is there anything else that you are relying on to
18 support your opinion that the inflammation caused
19 by talcum powder is the type of inflammation that
20 causes cancer?

21 A So there's additional references
22 mentioned in the report; Gates, Belot, Harper and
23 Saed. And then, in addition to that, there was
24 a --

1 Make sure I'm referring to the right
2 one.

3 So those were the -- those were the
4 primary references. And then, of course, there
5 were supporting materials and other earlier-cited
6 work.

7 But for the opinion regarding the type
8 of inflammation that is caused by exposure to
9 talc and as far as its specific relationship to
10 cancer, there's -- there's -- I would point to
11 the, at least in the Saed work, the specific
12 quantitation of a very well-known tumor marker,
13 CA 125, also known as mucin-16 elevation in that
14 work, and then, in the case of Gates, some of the
15 fundamental glutathione S-transferase has been
16 associated or has been observed as a higher risk.

17 And, so, that would -- those would be
18 some examples.

19 Q Are you aware of any animal study,
20 Dr. Levy, that shows the inflammation caused by
21 talcum powder causing precancerous changes?

22 MS. O'DELL:

23 Object to the form.

24 A I would have to review the -- a few of

1 the details, and I -- there -- I am aware
2 of -- mentioned earlier the Woodruff or Woodford,
3 the earlier 1971 paper where I couldn't remember
4 the author, is one of the earliest studies that I
5 came across that had -- it has an animal model
6 study.

7 MS. BROWN:

8 Q Doctor, is it your testimony that --

9 First of all, do you think it's -- that
10 in opining that there is a biologically plausible
11 mechanism by which talcum powder causes chronic
12 inflammation that can cause ovarian cancer, is it
13 necessary, in your mind, to be able to show in
14 animals that talcum powder does just that?

15 A That talcum powder causes inflammation?

16 Q That causes ovarian cancer.

17 A No, I don't -- I don't think that
18 that's -- that's certainly not a requirement.

19 And the reason I -- the reason I give that answer
20 is -- is quite simple; that there is a wide
21 diversity of animal model studies that have not
22 been able to mimic specifically or correctly
23 human cancer for both -- both from a detection
24 and most often from a treatment perspective,

1 meaning that, fundamentally, humans and most --
2 or at least the animal systems used as -- in
3 scientific modeling are different. Some of their
4 differences are due to different pathways, and
5 others of the differences are due to actually,
6 you know, fundamental immune system differences.

7 Q The Hamilton article that you
8 identified for me, we marked earlier in the
9 deposition as Exhibit 7. Do you recall that?

10 MS. O'DELL:

11 Counsel, would you mind just placing
12 the exhibits by the witness so he can refer to
13 them as he'd like, please.

14 A Yes, I recall this.

15 MS. BROWN:

16 Q And you would agree with me, Doctor,
17 that the Hamilton study that we discussed this
18 morning concluded that there were no neoplastic
19 changes in the animals that were injected with
20 talcum powder; correct?

21 MS. O'DELL:

22 Object to the form. Asked and
23 answered.

24 A No. No, I -- I wouldn't agree.

1 MS. BROWN:

2 Q What evidence in Hamilton, Doctor, are
3 you relying on to support your position that
4 Hamilton showed neoplastic changes in animals
5 injected with talc?

6 A Well, I'm not -- I'm not stating that
7 Hamilton specifically showed that.

8 What I'm stating is that -- that there
9 is a Hamilton study as an animal model system to
10 make the conclusion that, in this animal model
11 system, that talc or talcum powder does not -- or
12 that causes or does not cause ovarian cancer is
13 not -- it's -- it is -- it has limitations.

14 And, as we discussed a bit earlier, the
15 two limitations are the very limited time points
16 of the animals. And if we look at the relative
17 and observed time points that we know now, as far
18 as latency period, these are well short of
19 those -- of those periods, even by rat standards,
20 and then the number of treated animals is
21 relatively small at ten. So the...

22 Q Doctor, do you rely on the Hamilton
23 article to support your opinion that talcum
24 powder produces chronic inflammation that causes

1 ovarian cancer?

2 A No, I don't rely -- again, I don't rely
3 on any -- there's not a reliance on any singular
4 article.

5 Q Did not mean to suggest that, Doctor.

6 I asked you for the scientific support
7 that you have for the opinions you're giving in
8 this litigation, and one of the articles you
9 identified was the Hamilton article. Correct?

10 A Uh-huh. Yes.

11 Q And I -- and this Hamilton article, as
12 we discussed, at page 103, found no evidence of
13 neoplasm in the rats injected with talc. Right?

14 A They -- I -- I don't -- they did
15 not -- I don't recall seeing a description of
16 neoplasm in the Hamilton article.

17 Q Page 103, second column, begins with
18 "No evidence."

19 A "No evidence of cellular atypia."

20 Q Uh-huh. "And concludes that in no
21 ovary was there any evidence of frank neoplasia";
22 right?

23 A Yes. That's what's written in the
24 paper.

1 Q So this article looked at talc that was
2 injected into animals and found no evidence of
3 changes that lead to cancer. Correct?

4 MS. O'DELL:

5 Objection to form.

6 A Over the time period that they -- that
7 the study was performed, they did -- they did
8 not -- they did not report, and, in fact, as you
9 said, their statements are "no evidence of
10 cellular atypia or mitotic activity."

11 MS. BROWN:

12 Q So in opining, as you do in this case,
13 that talcum powder can biologically induce
14 chronic inflammation that causes ovarian cancer,
15 what methodology did you employ to consider the
16 findings of the Hamilton article?

17 A Well, I considered the findings of the
18 Hamilton article, as -- as referenced in the
19 report, primarily showing that talc has an
20 inflammatory or an immune response. And that was
21 the primary inclusion of the -- of the Hamilton
22 paper.

23 Q Not all inflammatory or immune
24 responses lead to cancer; right?

1 MS. O'DELL:

2 Objection. Asked and answered.

3 A As -- as we discussed, not -- not all
4 inflammatory responses have been shown to
5 conclusively lead to cancer. And, so...

6 MS. BROWN:

7 Q And Hamilton does not support the
8 opinion that the type of inflammatory response
9 that talc causes is the type that causes cancer.
10 Fair enough?

11 MS. O'DELL:

12 Object to the form.

13 A No. I would say that's unfair.
14 Because, again, the limitation of the Hamilton
15 study at the time it was performed was -- is a
16 very short timeline. So there is -- it is an
17 incomplete study in the sense that there is
18 certainly the possibility that the first aspect
19 or the first event that we're -- that we've been
20 discussing in cancer biology, the cellular damage
21 to lead to transformation, could have occurred in
22 some of the rat tissues but had not progressed
23 enough or had -- or had taken hold enough to
24 cause or to have that be detected in this

1 particular study performed in the early '80s.

2 And, furthermore, rat -- the rat model
3 for human cancer, since this study has been in
4 other cases, has some limitations as it relates
5 to how applicable it is to the human condition.

6 MS. BROWN:

7 Q The NTP study that you identified as
8 supporting your opinion, Doctor, that also does
9 not show evidence of neoplastic changes; is that
10 right?

11 MS. O'DELL:

12 Object to the form.

13 Doctor, please feel free to refer to
14 the study if you need to.

15 A Yeah. I'll do that now.

16 (DEPOSITION EXHIBIT NUMBER 15
17 WAS MARKED FOR IDENTIFICATION.)

18 MS. BROWN:

19 Q Doctor, we'll mark as Exhibit 15 to
20 your deposition the NTP study to which you were
21 referring.

22 A Uh-huh.

23 Q And this study, as well, does not show
24 evidence of neoplastic changes.

1 MS. O'DELL:

2 Object to the form.

3 Do you have a copy for me?

4 It's what number?

5 MS. BROWN:

6 Fifteen.

7 A I think the -- the important
8 distinction in this particular study is this was
9 an aerosol-based -- based study. It certainly
10 was longer than the Hamilton but was -- was not a
11 study that mimics the perineal use of talc.

12 MS. BROWN:

13 Q And, so, as it relates to your opinion
14 in this case, Doctor, that talc induces a chronic
15 inflammation that can lead to ovarian cancer, the
16 NTP study does not support that, does it?

17 MS. O'DELL:

18 Object to the form.

19 A I would say the study does support my
20 opinion regarding talc and its role in
21 inflammation. And if we refer to page 6 within
22 the first -- the first paragraph, beginning with
23 "Accumulations of macrophages."

24 MS. BROWN:

1 Q Did you review, Doctor, the --

2 And -- and what about the findings of
3 NTP support your opinion?

4 A Well, first, the inflammatory response,
5 given the evidence by the accumulation of
6 macrophages, and then, secondly, that in the
7 female rats, the incidences of alveolar and
8 bronchial or adenoma, carcinoma, and adenoma in
9 the 18-milligram-per-meter group were
10 significantly greater than those of controls.

11 Q So did you consider the FDA's findings
12 as it relates to the evaluation of the NTP study?

13 MS. O'DELL:

14 Object to the form. Vague.

15 A Which -- which FDA?

16 MS. BROWN:

17 Q Have you considered, in connection with
18 this case, the FDA's response to the 2014
19 citizens petition?

20 A Yes. That's familiar. And if I recall
21 correctly --

22 Or do you have -- is that handy?

23 Q We'll mark that as Exhibit 16, Doctor.

24 (DEPOSITION EXHIBIT NUMBER 16

1 WAS MARKED FOR IDENTIFICATION.)

2 MS. BROWN:

3 Q The reason I want to talk to you about
4 this is it contains a review of the NTP study we
5 were just discussing.

6 First of all, did you consider this
7 document in connection with your opinions in this
8 case?

9 A Yes, this document's familiar.

10 Q Okay. And do you recall that a cancer
11 prevention coalition wrote the FDA requesting
12 that a warning label be placed on talcum powder
13 products?

14 A Yes.

15 Q And do you recall, as evidenced on
16 page 1, the FDA reviewed the data as it related
17 to that question?

18 A I -- I recall that the FDA reviewed the
19 data and determined that it was insufficient, and
20 they did not identify any new compelling
21 literature at the time. But this was in 2014.

22 Q And the NTP --

23 MS. O'DELL:

24 Excuse me, counsel.

1 Were you finished? If you're finished,
2 that's fine. I just didn't know if you completed
3 your --

4 A I'm just reading. There was one
5 other -- I recall --

6 MS. BROWN:

7 Q Doctor, the NTP study that you pointed
8 us to was from 1993. Is that right?

9 A I believe that's correct.

10 Q All right. And one of the things that
11 the FDA did in this letter of 2014 is reviewed
12 that study; correct?

13 A Yes.

14 Q And I'll direct you to page 3 of 7.
15 And what the FDA concluded was that the study
16 lacked convincing scientific support because of
17 serious flaws in its design and conduct.

18 Do you see that?

19 MS. O'DELL:

20 Where are you reading? Sorry.

21 MS. BROWN:

22 Page 3. Page 3.

23 MS. O'DELL:

24 Oh. Page 3. Sorry. I thought you

1 said page 2. I'm sorry.

2 MS. BROWN:

3 Q Do you see that, Doctor?

4 A Starting with --

5 Q Bottom of page 3 --

6 A -- under toxicology findings?

7 Q So, to orient us here, Doctor, you
8 pointed, as evidence of support of your opinions
9 in this case, to the NTP study. Right?

10 A Correct.

11 Q And the folks who wrote to the FDA
12 requesting a warning on talc, they, too, pointed
13 to that study; right?

14 A Yes.

15 Q All right. And, so, the FDA reviewed
16 that study and, in the letter denying the
17 citizens petition, included its critique of that
18 study; correct?

19 A Correct.

20 Q And one of the things the FDA concluded
21 was that the study had serious flaws. True?

22 MS. O'DELL:

23 Objection to form.

24 A I don't -- do you -- I don't see where

1 the FDA claimed serious flaws.

2 MS. BROWN:

3 Q At the bottom of page 3 --

4 A I see.

5 Q -- the sentence that begins, "However,
6 this study lacks convincing scientific support
7 because of serious flaws in its design and
8 conduct -- and conduct."

9 Do you see that?

10 A I do.

11 Q And one of the things the FDA points to
12 is that the investigators used micronized talc
13 instead of consumer grade talc, resulting in the
14 experimental protocol not being reflective of
15 human exposure conditions in terms of particle
16 size.

17 Do you see that?

18 A I do.

19 Q Have you made a determination in this
20 case, sir, about the size of the particles in
21 talcum powder products?

22 A I -- I've not made that distinction.

23 And --

24 Q There's --

1 A And, furthermore, I think the --
2 importantly, the -- the flaws that the FDA points
3 out are, you know, not in disagreement with
4 our -- with our discussions surrounding both the
5 inflammatory response and then some of the
6 results there. I don't -- I don't see as a
7 concern --

8 In fact, the -- it appears the FDA does
9 not disagree with the observation of the evidence
10 of carcinogenic activity in the non-asbestiform
11 talc. I think they --

12 I share --

13 Q Let's focus back on the question,
14 Doctor.

15 MS. O'DELL:

16 Excuse me. Let him finish his answer.
17 He's not finished.

18 A So, the, you know, the serious flaws
19 were the, I think, in this case, the specific
20 inclusion of nonasbestos talc and use of
21 micronized talc instead of consumer grade. So I
22 think in that -- in that sense, it's not
23 surprising that it had a different -- perhaps a
24 different response than may be observed with

1 consumer products or talc that have -- may have
2 contaminants, whether it be asbestos or other.

3 MS. BROWN:

4 Q Do you remember the question I asked,
5 Doctor?

6 A Perhaps it would be helpful to restate.

7 Q I think, probably.

8 I asked if you had made a determination
9 in this case about the size of the particles in
10 talcum powder products.

11 A I -- so as far -- a determination, no.
12 I would -- I would say I have had an opportunity
13 to, you know, review or become more educated in
14 the diversity of talc products and the
15 interesting geographic relationship to different
16 size particles and -- in the presence or absence
17 of asbestiform particles in talc, which was a,
18 you know, fascinating area to become educated in.

19 As far as examining that in each of the
20 individual studies, I certainly was able to pay
21 attention to earlier or later studies as it
22 applied to when there was a specific description
23 of the talc, such as in the NTP study where
24 there -- that was one of the few that had a

1 specific determination.

2 But I was basing my opinions on the
3 general behavior, summarized behavior of talc
4 based on the available evidence.

5 Q In forming your opinions in this case,
6 Doctor, have you concluded that a particular
7 route of exposure is more likely when women are
8 using talcum powder products perineally?

9 MS. O'DELL:

10 Object to the form.

11 A Certainly it would seem logical that
12 the route of talc exposure would be related to
13 the area that the talc is used.

14 MS. BROWN:

15 Q As such, do you believe and have you
16 assumed for purposes in your -- of your opinions
17 in this case that talc more likely migrates from
18 the perineum to the ovaries, as opposed to talc
19 being inhaled and then traveling down to the
20 ovaries?

21 A The evidence I've seen would suggest
22 that that migration that you described from the
23 perineum through the vagina into the fallopian
24 tubes into the ovary is certainly far more likely

1 when -- when used in the perineum compared to
2 inhalation.

3 But I have not seen a study that tried
4 to distinguish that in terms of having an exposed
5 group who inhaled talc only and then looked for
6 evidence of the presence in the ovary.

7 Q Back to the FDA document we were
8 discussing, Doctor, the FDA's critique of the NTP
9 study continues on page 4, where the FDA
10 identifies that the investigators conceded they
11 have problems with the aerosol generation system
12 and that the study did not include positive and
13 negative dust controls.

14 Did you consider those critiques in
15 evaluating the NTP study in this case?

16 MS. O'DELL:

17 Object to the form.

18 A Well, I -- I certainly considered --
19 you know, considered them in -- as -- as I would
20 consider any -- any other evidence or opinion
21 on -- on these relevant subjects.

22 MS. BROWN:

23 Q The FDA went on to conclude, Doctor,
24 that, in light of the shortcoming, a panel of

1 experts at the 1994 IS RTP/FDA workshop declared
2 that the 1993 NTP study has no relevance to human
3 risk.

4 Do you share that conclusion?

5 MS. O'DELL:

6 Object to the form.

7 A I do not. And I think, importantly,
8 you know, even there at the bottom of page 4,
9 their point number 4 saying a cogent biological
10 mechanism by which talc might lead to ovarian
11 cancer is lacking.

12 MS. BROWN:

13 Q Uh-huh.

14 A I believe, as we're discussing today,
15 subsequent research and subsequent studies
16 have -- and including my report, have helped
17 define that plausible biological mechanism
18 which -- by which talc may lead to ovarian
19 cancer.

20 Q In answering my question, Doctor, you
21 pointed to a different portion of the same page
22 we were discussing; correct?

23 A Correct.

24 Q And what you pointed to was the FDA's

1 conclusion here in 2014 that a cogent biological
2 mechanism by which talc might lead to ovarian
3 cancer is lacking. Correct?

4 MS. O'DELL:

5 Object to the form.

6 A I -- I would disagree in the general
7 nature of your statement and clarify it by saying
8 the FDA found a lack of that mechanism based on
9 the submitted literature of the citizen petition.

10 MS. BROWN:

11 Q So do you understand, Doctor, in
12 evaluating the FDA's response, that they, in
13 fact, did their own investigation in addition to
14 the literature that was provided to them at the
15 time?

16 MS. O'DELL:

17 Objection. Misstates the record.

18 A Well, my reading of it, it says
19 they -- that their -- that the scientific
20 literature considered was submitted in support of
21 both citizen petitions. And...

22 MS. BROWN:

23 Q Are you finished, Doctor?

24 A Yes. I was just looking to see if

1 there was a notation about further --

2 Q I'll direct you, Doctor, to page 4, the
3 second full paragraph that begins "In addition,
4 the FDA stated."

5 "In addition, we reviewed relevant
6 toxicity literature (consisting of 15 articles
7 from 1980 to 2008) not cited in your petition to
8 determine if there was additional support at this
9 point in time for your suggested warning label."

10 Do you see that?

11 A I do.

12 Q And, based on the FDA's review of all
13 the literature that they investigated at the
14 time, they concluded that a cogent biological
15 mechanism by which talc might lead to ovarian
16 cancer was lacking. Right?

17 MS. O'DELL:

18 Objection to form.

19 MS. BROWN:

20 Q That was their conclusion; correct?

21 A Yes, as written, that was their -- that
22 was the FDA's conclusion.

23 Q And you, Dr. Levy, disagree with that
24 conclusion; correct?

1 A I -- I disagree with the -- or I -- I
2 have found, based on a review of the literature,
3 that there are now additional supporting studies
4 that would -- that would refute some of these
5 conclusions of -- by the FDA review.

6 Q And explain to us, then, Doctor, what
7 methodology you employed or what research you
8 conducted to reach a conclusion different from
9 the FDA's conclusion in 2014.

10 A I think, similar to what the FDA
11 described, my review is of the literature now,
12 you know, through 2018, examining the available
13 information regarding inflammatory response to
14 talc and then talc exposure as it relates
15 to -- to the initiation of progression of cancer.

16 Q Dr. Leavy -- Dr. Levy, do you think
17 that the FDA, in concluding, as they did in 2014,
18 that a cogent biological mechanism by which talc
19 might lead to ovarian cancer is lacking, do you
20 think they were wrong at that time?

21 A I would -- I -- I would say that they
22 were incomplete at that time. And, in fact, you
23 know, one of the --

24 If we -- if we look at page 5 in the

1 one, two -- third full paragraph beginning with
2 "while there exists," where the FDA does agree
3 about the -- that it's plausible that perineal
4 talc and other particulates reach the endometrial
5 cavity and -- and associated organs and may
6 elicit a foreign-body-type reaction and
7 inflammatory response that in some exposed women
8 may progress to epithelial cancers. What they do
9 state, "However, there has been no conclusive
10 evidence to support causality."

11 So I would suggest that this paragraph
12 is in support of the biologically plausible
13 mechanism that I included in the report and
14 that -- and, as we've been discussing, I
15 haven't -- we -- we've not been discussing a
16 causal or a formal causal evaluation.

17 Q What information did you rely on,
18 Doctor, in reaching the conclusion that there is
19 a biological mechanism that the FDA did not?

20 MS. O'DELL:

21 Object to the form. Misstates his
22 testimony.

23 A I'm stating that the -- as we
24 discussed, as we've been discussing today, the --

1 the response to talc -- the response to talc
2 exposure as an inflammatory response is supported
3 by a number of studies, including the NTP study,
4 which, although the FDA had some concerns with,
5 the FDA also made statements regarding the
6 exposure to talc and other particulates having an
7 inflammatory response and that some exposed
8 women's may have progressed to epithelial
9 cancers.

10 So, again, they're -- I think
11 they -- they're in agreement there. So even the
12 concerns with the study withstanding, there's --
13 there's -- there's -- I still -- I still think
14 the FDA report is in support of the mechanism
15 that we've been discussing.

16 MS. BROWN:

17 Q The FDA concludes that a cogent
18 biological mechanism by which talc might lead to
19 ovarian cancer is lacking, do they not?

20 MS. O'DELL:

21 Objection to form. Asked and answered.

22 A But I would al- -- I would say the FDA
23 contr- -- perhaps contradicts itself later in the
24 same document, stating that there is both an

1 inflammatory response and that in some exposed
2 women they may progress to epithelial cancer.

3 MS. BROWN:

4 Q Other than the Woodruff article,
5 Doctor, are you aware of any other study in
6 animals that shows inflammation leading to
7 cancer?

8 MS. O'DELL:

9 Objection to form. Other than those
10 he's mentioned?

11 A Yeah. I -- I would have to -- that
12 would -- that would require review of the
13 literature to -- to speak generally to animal
14 studies and inflammation leading to cancer.

15 MS. BROWN:

16 Q Let me rephrase.

17 In terms of your opinion here that talc
18 causes chronic inflammation that causes ovarian
19 cancer, you identified the Hamilton study, the
20 NTP study, and the Woodruff study as animal
21 studies that support that view. True?

22 A I identified those studies as
23 supportive of my -- of my opinion, yes.

24 Q Are you aware of any additional animal

1 studies on which you're relying?

2 A Not -- not for the contents of the
3 report. Not that I'm aware of. I think we've --
4 we've already discussed some of the other
5 references contained in the report
6 below and -- or at least by mention and Gates.

7 (DEPOSITION EXHIBIT NUMBER 17
8 WAS MARKED FOR IDENTIFICATION.)

9 MS. BROWN:

10 Q I'm gonna mark as Exhibit 17 to your
11 deposition the Buz'Zard study that you mentioned
12 a moment ago. Do you recall that?

13 A Yes.

14 Q Do you rely on the Buz'Zard study in
15 supporting your view that chronic inflammation
16 from talcum powder use can cause ovarian cancer?

17 MS. O'DELL:

18 17?

19 MS. BROWN:

20 Yes.

21 A Sorry. Can you restate your question?
22 It wasn't...

23 MS. BROWN:

24 Q Do you rely on what we've marked as

1 Exhibit 17, the Buz'Zard study, to support your
2 view that talcum powder causes chronic
3 inflammation that leads to ovarian cancer?

4 MS. O'DELL:

5 Object to the form.

6 A As we've discussed, not singularly, but
7 the -- as part -- as part of a complete picture
8 of talc causing reactive oxygen species
9 generation and other inflammatory responses,
10 certainly this is a study that supports that
11 opinion.

12 MS. BROWN:

13 Q Did you consider the type of cells that
14 were evaluated in the Buz'Zard study?

15 MS. O'DELL:

16 Objection to form. Vague.

17 A Certainly in terms of the overall
18 experimental design.

19 MS. BROWN:

20 Q Did those -- were those normal human
21 ovarian cells?

22 A The -- the author has labeled them as
23 normal human ovarian cells. But the -- you know,
24 one of the key characteristics and similar to our

1 comments on -- on animal systems is all -- all
2 in vitro or in vivo studies that are using cell
3 lines or animals have limitations. And in this
4 case, you know, cell lines are particularly
5 notorious in research in general for
6 their -- for -- having to use care in extending
7 findings to, you know, broad mechanisms in a --
8 in a complex organism or in the human body.

9 Q Sure.

10 What you're -- what you're saying is
11 you've got to be careful taking the findings from
12 one cell study and extrapolating that to humans.
13 Fair?

14 MS. O'DELL:

15 Object to the form.

16 A The -- I think you have to be careful
17 in evaluating each study in using the relevant
18 components of that study and observations in that
19 study as part of an overall mechanism and whether
20 it's supportive or refutes such a mechanism.

21 So --

22 MS. BROWN:

23 Q Did -- did you exercise that care here
24 as it relates to the Buz'Zard study?

1 A So the Buz'Zard study, you know,
2 primarily, as -- as referenced, was to illustrate
3 a study that showed an increase in reactive
4 oxygen species generation, and that's the -- the
5 primary purpose, or I should say primary
6 observation on the -- from this.

7 Now, certainly, the study contained
8 more observations than that and certainly had
9 some -- you know, a number of other components.

10 Q How does the Buz'Zard study support
11 your view that talcum powder causes chronic
12 inflammation that causes ovarian cancer?

13 A So the Buz'Zard study supports the view
14 that exposure to talcum powder causes an
15 inflammatory response.

16 Q And that inflammatory response you saw
17 in the Buz'Zard study does not increase with
18 increasing doses of talcum powder. Correct?

19 A I have to review. I believe that -- I
20 believe their figures suggest --

21 You know, are you referring
22 specifically to their reaction -- reactive oxygen
23 specie generation?

24 Q Correct.

1 MS. O'DELL:

2 Figure 3.

3 A Figure 3?

4 The one interesting observation in
5 these two figures, both Figure 3A and Figure 3B,
6 being the percentage of reactive oxygen specie
7 generation in two different cell types, one in --
8 one in Panel A and one in Panel B, is -- what I
9 did not see included, if I --

10 And I'm reading to see if I recall
11 correctly.

12 -- was a -- the -- the cell viability
13 assay that they use for normalization has
14 a -- somewhat of a limitation in that it -- it
15 doesn't measure cell senescence. It only
16 measures cell death. And, so, they -- not to
17 dis- -- not that I disagree with your observation
18 that it did not show the sig- -- significant
19 increase, but there is the possibility that the
20 reason that you see an actual decrease in the RS
21 generation at the higher doses of talc is that
22 cells have gone senescent and are essentially no
23 longer responding to that increased dose.

24 So I think there's at least two

1 different ways to interpret some of these
2 results. But I don't disagree with your
3 observations regarding Figure 3.

4 MS. BROWN:

5 Q This study was conducted in a
6 nutritional lab, not a cancer lab. True?

7 A I'm -- I'm not aware of the type of
8 laboratory or even the...

9 Q And the study was -- the purpose of the
10 study was to assess whether there was a certain
11 effect of pine bark supplement? Is that right?

12 MS. O'DELL:

13 Objection to form.

14 A They were looking at the -- the effect
15 of a proprietary -- as stated by the authors, a
16 proprietary mixture of water soluble
17 bioflavonoids extracted from French maritime pine
18 bark.

19 MS. BROWN:

20 Q Uh-huh.

21 And did you investigate whether the
22 ovarian cells that they used here were
23 genetically altered?

24 A No, I did not investigate that.

1 Q Did you --

2 I'm sorry. Were you done?

3 A No. I would say it's fair -- it's fair
4 to say that, you know, that the -- whether
5 they're genetically altered or not, the -- the --
6 you know, the same potential limitations as far
7 as extrapolation to the human system would apply
8 for any signs.

9 But, again, the purpose of the Buz'Zard
10 study, as -- as referenced in the report, was to
11 indicate that there are studies that have shown
12 an increase in reactive oxygen specie generation
13 under exposure to -- to talc. And I think the
14 study is reasonably clear on that increase
15 relative to control.

16 Q Except what this study showed, Doctor,
17 is the more talc you give, the decrease from
18 baseline in the reactive oxygen species.

19 Correct?

20 MS. O'DELL:

21 Object to the form. Asked and
22 answered. Misstates the testimony.

23 MS. BROWN:

24 Q Take a look at Figure 3; right, Doctor?

1 A No. I agree. But, as stated, and an
2 important clarification is whether that decrease
3 is significant relative to the biology is -- is
4 unknown.

5 Q Right.

6 This study certainly does not
7 conclusively show that the more talc you give,
8 the more ROS is generated. Correct?

9 MS. O'DELL:

10 Object to the form.

11 A In these particular cell lines under
12 these conditions, the -- the study certainly did
13 not draw that conclusion.

14 MS. BROWN:

15 Q In fact, what this study shows is the
16 more talc you give, the less of -- of ROS
17 generation you have. Doesn't it?

18 MS. O'DELL:

19 Object to the form.

20 A I think importantly in this study, the
21 time dependency for each of the doses is more
22 important at the doses rather than comparing dose
23 to dose.

24 MS. BROWN:

1 Q My question was, Doctor, what this
2 study shows is the more talc you give, the less
3 ROS generation there is. True?

4 MS. O'DELL:

5 Objection to form.

6 A Again, under -- under the conditions of
7 this particular study.

8 MS. BROWN:

9 Q Do you think the Buz'Zard study is
10 scientifically reliable?

11 A I have no basis to -- to suggest that
12 it's -- that it's not reliable.

13 Q Do you think that --

14 A But I think there -- it does -- if
15 there is a -- as we discussed earlier, an
16 importance to not overgeneralize conclusions or
17 lack of conclusions as, you know, outside of the
18 system under study.

19 Q If -- I want you to assume that the
20 Buz'Zard study used genetically altered ovarian
21 cells that did not have the p53 protein. Would
22 that affect your analysis of Buz'Zard?

23 MS. O'DELL:

24 Object to the form.

1 A Well, that's -- that's an impossible
2 question. Like you can't have --

3 Well, you can't call a cell type a
4 normal ovarian cell and -- absent p53 protein.
5 You're -- it'd be -- you're fundamentally
6 changing the biology of the cell as it relates to
7 ovarian cancer or cancer in general.

8 MS. BROWN:

9 Q Because p53 is something that you have
10 in your genes that prevents against ovarian
11 cancer. True?

12 MS. O'DELL:

13 Objection.

14 A So p5- -- p53 is a well-known, often
15 mutated gene in a number of human cancers.

16 MS. BROWN:

17 Q And, so, if the ovarian cells that were
18 studied in Buz'Zard did not have p53, it will
19 call into question the study. Fair?

20 MS. O'DELL:

21 Object to the form.

22 A It would be difficult to answer. From
23 the perspective of the presence or absence
24 of -- of p53 having an effect on the ability of a

1 cell to generate reactive oxygen species under --
2 under exposure to a substance like talcum powder
3 would need to be tested directly.

4 MS. BROWN:

5 Q Fair to say, in your mind, a cell
6 missing p53 is not a normal human ovarian cell.
7 True?

8 A That is true.

9 (DEPOSITION EXHIBIT NUMBER 18
10 WAS MARKED FOR IDENTIFICATION.)

11 MS. BROWN:

12 Q Handing you what we've marked as
13 Exhibit 18 to your deposition, it's a review
14 article titled "Perineal Talc Use and Ovarian
15 Cancer," by Ross Penninkilampi.

16 Do you see that?

17 A I do.

18 Q This is an article that you cited in
19 your report; correct?

20 A Correct.

21 Q Does this article support your view
22 that there is a biolo -- in part --

23 Strike that.

24 Does this article, in part, support

1 your opinion in this case that there is a
2 biologically plausible mechanism by which talcum
3 powder can cause ovarian cancer which can
4 cause --

5 Strike that. Gonna do it again.

6 Does this article support your view, in
7 part, that talcum powder can cause chronic
8 inflammation that can cause ovarian cancer?

9 A This is an article I considered in
10 the -- in the overall review and, in the
11 conclusions of this article, found a -- an
12 association between perineal talc use and ovarian
13 cancer, according to the authors.

14 So it was supportive of the proposed
15 mechanism but was, again, in part.

16 Q And, on page 13 and 14 of your report,
17 you, in fact, reference the Penninkilampi study
18 and some of its conclusions; correct?

19 A Correct. On the -- on the bottom of
20 page 13, yes.

21 Q And what was the purpose of including
22 this description of Penninkilampi in your expert
23 report, Doctor?

24 A Just to be sure to be -- to include

1 available literature and, in this case, review a
2 meta-analysis of some reasonably large-scale
3 studies to try to bring the proposed biologically
4 plausible mechanism and include the -- the
5 available epidemiological information for those,
6 such as the Penninkilampi and Eslick paper we're
7 discussing.

8 Q What methodology did you employ in
9 terms of reviewing the Penninkilampi findings as
10 it relates to the question you addressed in your
11 report?

12 MS. O'DELL:

13 Object to the form.

14 A I -- I used the same methodology for
15 the other studies as a review of the paper and
16 its -- and its methods and conclusions.

17 MS. BROWN:

18 Q Do you believe this review, systematic
19 review and meta-analysis, provides evidence that
20 there's a biologically plausible mechanism by
21 which talc can cause ovarian cancer?

22 A Yes. It provided -- it shows an
23 association between talc use and ovarian cancer.
24 I don't -- I don't believe this particular study

1 goes on to specifically elucidate causation, but
2 it certainly shows the association.

3 Q Well, the study specifically says that
4 causation cannot be found, based on the results.
5 Right?

6 MS. O'DELL:

7 Objection to form.

8 MS. BROWN:

9 Q If you look at page 42, Doctor, the
10 very end of that first paragraph, "A certain
11 causal link between talc use and ovarian cancer
12 has not been established."

13 Do you see that?

14 MS. O'DELL:

15 Where are you? Page 42. Where are you
16 reading, please?

17 MS. BROWN:

18 Page 42, the end of the first
19 paragraph.

20 A Yes, I see that.

21 MS. BROWN:

22 Q Do you agree with that statement,
23 Doctor, that a causal link between talc use and
24 ovarian cancer has not yet been established?

1 MS. O'DELL:

2 Objection.

3 A No, I wouldn't. But, again, my review
4 of this was to tie the biologically plausible
5 mechanism to, you know, human observation, not
6 provide a evaluation of the -- of the causal
7 link.

8 And I think the -- I would suspect that
9 the --

10 I'm also not aware of a study that has
11 been able to -- or a -- or a -- what would be
12 necessary --

13 I'm not aware of a study that has been
14 able to provide all of the recognized and
15 established methodology for causation and have
16 that applied in -- in talc.

17 MS. BROWN:

18 Q You're not aware of any study in the
19 talc epidemiology that has concluded that talcum
20 powder causes ovarian cancer; correct?

21 MS. O'DELL:

22 Objection to form.

23 A I'm aware of a number of studies that
24 have shown a strong correlation between the two.

1 But I would have to defer to the epidemiology
2 expert witnesses as to their opinion on
3 causation.

4 MS. BROWN:

5 Q One of the things you told us that you
6 reviewed in connection with your opinion was the
7 talc epidemiology. Is that right?

8 A That's right.

9 Q Did you conduct a review of all of the
10 available epidemiology on talcum powder use and
11 ovarian cancer?

12 A I certainly tried to review it as
13 comprehensively as -- as possible.

14 Q And, in connection with that review,
15 you'll agree there is not a single study that
16 concludes there is a causal association between
17 talcum powder use and ovarian cancer; correct?

18 MS. O'DELL:

19 Objection to form.

20 A So I would -- I would -- interestingly,
21 there -- it's -- it becomes a -- as more -- as
22 more and more information has become available
23 over the last few years, that becomes a more and
24 more difficult bar to meet, simply because, to

1 examine that comprehensively, when you consider
2 the etiology of a disease and the latency periods
3 that have been observed in ovarian cancer in
4 general and the meta review by both this earlier
5 paper by Penninkilampi and then their subsequent
6 later work, you have a challenge of a -- in a
7 cohort study, a disease that is somewhat rare,
8 coupled with a exposure and latency period that's
9 been, in the -- in the limited number of studies
10 that have looked at this, appears to be quite
11 long, and then when you couple in the -- the
12 ethical concerns of actually performing a trial,
13 where it becomes a very difficult causation bar
14 to reach.

15 And, so, instead, we rely on the
16 case -- the available case-control data and then
17 systematic and meta-analysis reviews such as some
18 of the epidemiologists have performed to make
19 assessments into the likelihood that -- and the
20 strength of the association between talc use and
21 ovarian cancer.

22 Q Are you intending to provide an opinion
23 on the strength of the association between talc
24 use and ovarian cancer as evidenced in the

1 epidemiology?

2 MS. O'DELL:

3 Object to the form.

4 A No. My -- my opinions are limited to
5 the biologically plausible mechanism and then
6 examining whether that biologically plausible
7 mechanism presented is supported by observations
8 in -- in available human studies.

9 MS. BROWN:

10 Q And when you say your opinion is
11 limited to a biological plausible mechanism, are
12 you talking of the theoretical concept or are you
13 talking about in the context of women using
14 talcum powder perineally?

15 A In the context --

16 MS. O'DELL:

17 Object to the form.

18 THE WITNESS:

19 Sorry.

20 MS. O'DELL:

21 Excuse me.

22 A In the -- in the context of women using
23 talcum powder perineally specifically, and
24 then -- and then certainly also the -- some of

1 the fundamental aspects of that mechanism may
2 apply to other exposures as well.

3 MS. BROWN:

4 Q Like what?

5 A Well, the -- the other exposure we've
6 been discussing, in -- in that some of the
7 studies looked at inhalation exposure, et cetera.

8 But the primary review and the primary
9 opinion is based on the perineal use of talcum
10 powder and that exposure that, as -- as we
11 discussed earlier, has a -- certainly a strong
12 association with perineal use and an exposure --
13 exposure in the ovaries.

14 Q Your opinion is that if a woman uses
15 talcum powder perineally, there is a biologically
16 plausible mechanism by which enough talcum powder
17 can migrate from outside of her vagina to her
18 ovary to cause chronic inflammation that can lead
19 to ovarian cancer?

20 MS. O'DELL:

21 Object to the form.

22 A So I'd say that the first part of your
23 question is well established and included in the
24 statements from FDA and others that that

1 migration does occur.

2 And then the next step in the -- in the
3 mechanism is that that causes inflammation which,
4 again, as we've discussed, in a number of
5 studies, that the inflammation occurs and then,
6 in these human studies, in their systematic
7 review, that there is a clear association or a --
8 a observed association between perineal use of
9 talc and the detection of ovarian cancer at some
10 point in the -- in the women's lives and, in the
11 case of the Penninkilampi, with a relationship to
12 the number of lifetime applications.

13 So considering those things together,
14 yes, there is a biologically plausible mechanism
15 for perineal talc use through to ovarian cancer.
16 MS. BROWN:

17 Q Have you -- is -- is your opinion that
18 there's a biologically plausible mechanism
19 dependent on a particular number of years of
20 perineal use?

21 MS. O'DELL:

22 Objection to form.

23 A The -- so the -- as we just discussed,
24 there's no -- I can't point to a formal clinical

1 trial that would examine that in a well-powered
2 fashion to answer that question directly. And,
3 certainly, as of today, there would be some
4 significant ethical concerns with that design.

5 So, instead, we rely on the cohort and
6 case-control studies that are available. And
7 those, again, studies are supporting an
8 association between talc use and ovarian cancer.

9 MS. BROWN:

10 Q Right. But I'm talking about for your
11 opinion that it's biologically plausible for
12 perineal use of talc to cause ovarian cancer,
13 have you made a determination, in your mind, of
14 how long that perineal use has to take place for?

15 MS. O'DELL:

16 Object to the form.

17 A I wasn't asked to provide -- to provide
18 that opinion on -- and it -- on that length or
19 exposure or duration.

20 Again, it was -- the focus was on the
21 biologically plausible mechanism that if you have
22 a single exposure and that -- that that single
23 exposure through to any other may be sufficient
24 to trigger that mechanism.

1 MS. BROWN:

2 Q That's helpful, Doctor.

3 So, as I understand your opinion, your
4 piece of the puzzle here was to look at whether
5 one single application of talcum powder to the
6 perineum could lead to chronic inflammation that
7 could cause ovarian cancer.

8 MS. O'DELL:

9 Objection.

10 MS. BROWN:

11 Q Correct?

12 A No, no.

13 MS. O'DELL:

14 Object to the form of the question.

15 A No. That's not my -- my statement.

16 My statement was that, based on the
17 evidence available, that there's a biologically
18 plausible mechanism for the -- for the cellular
19 changes that -- that is independent of the
20 exposure.

21 MS. BROWN:

22 Q You've made a determin- --

23 A But certainly a single exposure would
24 be the physically minimum number. And I

1 believe -- I think we --

2 Q That's what I want to understand. And
3 how you -- how you make this biological
4 plausibility determination is to evaluate a
5 single exposure? Is that right?

6 MS. O'DELL:

7 Object to the form.

8 A No.

9 MS. O'DELL:

10 Misstates his testimony.

11 A That's -- that's not what I'm stating.

12 My -- my statement is that the -- the
13 biologically plausible mechanism is a mechanism
14 that is independent of the exposure and that, as
15 part of the description of that mechanism and the
16 evaluation of the studies supporting that
17 mechanism through an inflammatory response, the
18 question of exposure, number, and duration,
19 length of time, et cetera, would be a separate
20 evaluation.

21 MS. BROWN:

22 Q Is your opinion that talcum powder
23 products cause chronic inflammation that cause
24 ovarian cancer limited to perineal use, or have

1 you also evaluated body use of talcum powder
2 products?

3 MS. O'DELL:

4 Object to the form.

5 A My -- my focus was on the perineal use,
6 and that's where the majority of the studies
7 have -- have examined. So the focus was on
8 perineal use of talcum powder.

9 MS. BROWN:

10 Q And in conducting that evaluation, the
11 results of which are contained in your report,
12 you did not endeavor to quantify how much talcum
13 powder used perineally could possibly migrate to
14 the ovaries; is that right?

15 MS. O'DELL:

16 Object to the form. Asked and answered
17 maybe ten times already today.

18 But you may answer the question.

19 A Yeah. I -- I wasn't asked to -- to
20 provide that opinion or attempt that
21 quantitation.

22 MS. BROWN:

23 Q So when you conduct your analysis of
24 whether something can biologically cause an

1 effect, it doesn't matter at all how much of the
2 product is used?

3 MS. O'DELL:

4 Objection.

5 MS. BROWN:

6 Q Do you see what I'm struggling with?
7 Can you help me understand? If I'm trying to
8 figure out does X cause Y, it sounds like what
9 you're saying is it doesn't matter how much X you
10 have.

11 MS. O'DELL:

12 Objection to form.

13 A So we're -- we're talking about
14 mech- -- so mechanistic action --

15 MS. BROWN:

16 Q Okay.

17 A -- which means the -- you set aside the
18 "how much." And the question is, from -- on a
19 molecular level, can the presence of a particular
20 compound in a particular location cause a
21 biological effect. And, so, that is the primary
22 focus of the opinion in the -- in the paper or --
23 sorry -- in my report.

24 And then extending that to how much,

1 how long, and the dur- -- and then the intensity
2 or duration of the biological effect, again, is a
3 separate -- would be a separate discussion or
4 separate study.

5 So, again, to clarify, the focus had
6 been on that -- some of the fundamental
7 mechanisms, talc -- a talcum powder exposure to
8 an inflammatory response to the inflammatory
9 response causing cancer.

10 Again, the -- I would refer to and
11 defer to the other experts in epidemiology
12 regarding their opinions on the validity of
13 the asso- -- validity and strength of the
14 associations, again, from a formal epidemiology
15 perspective.

16 My review of those studies has ind- --
17 has relied on their conclusions, and, then, in my
18 own review of their -- of their methodology
19 showing a increasing association, that is the
20 bookends of my -- of the mechanism I proposed.

21 So what this study is looking at is
22 perineal use of talc, getting cancer.

23 The -- what I've proposed is in the
24 middle. But this, again, the epidemiology

1 studies are asking how many times, what, and
2 where, but there's been no evaluation that I'm
3 aware of that looks at exactly how the talc was
4 applied, when and where. Instead, it was asked
5 number of lifetime applications, duration of use,
6 and examining latency period.

7 And when I examine that information
8 from the perspective of that biological
9 mechanism, I, you know, notice some parallels in
10 between latency period averaging roughly twenty
11 years, which -- which mimics somewhat what's
12 observed in the asbestos field as far as, you
13 know, lung effect latency.

14 And then that continues into the
15 constituent -- or the other constituent
16 components of some of the products, including
17 testing into asbestos and some of the -- and
18 heavy metal exposure, et cetera, that those are,
19 again, supportive and offer a potential
20 amplifying effect in that -- in that mechanism,
21 given the nature of those other components.

22 Q What's the scientific support for the
23 amplification effect you just described?

24 A Just that the presence of

1 more -- the --

2 So if we extend beyond the opinion that
3 talc, as a com- -- as a singular compound, causes
4 inflammation and then also, based on the reviewed
5 expert reports, find that testing of talc has
6 been shown to contain asbestos or asbestos
7 fibers, that the presence of now two potential
8 insulting --

9 I'm making a hypothesis or making a
10 statement that the -- you can have -- the more
11 biologically active compounds you have in an
12 exposure such as talc plus asbestos plus chromium
13 and then plus a milieu of chemicals that are in
14 fragrances may have an amplification effect on
15 that exposure and as part of that overall
16 biological mechanism.

17 Q Are you relying on a particular article
18 or any published scientific support for the
19 amplification argument?

20 MS. O'DELL:

21 Object to the form. He's answered the
22 question.

23 A No. I -- I don't know of a study that
24 is delineated. The -- it would be synthesizing

1 that opinion from the observations of a couple of
2 different studies, including the recent Saed
3 paper that did look at the specific consumer
4 product every -- you know, showing a -- if we do
5 it by way of comparison, between the Buz'Zard
6 paper and the recent Saed, seemingly a larger
7 magnitude of reactive oxygen species generation.
8 But, again, that is a -- extrapolating against
9 two different studies.

10 Q Do you --

11 MS. O'DELL:

12 Excuse me. We've been going about an
13 hour and 20 minutes, maybe a little more.

14 MS. BROWN:

15 I think a little less. But I'm gonna
16 finish up. Then we'll take a quick break.

17 Q Does that work for you, Doctor?

18 I just want to finish Penninkilampi if
19 we can.

20 MS. O'DELL:

21 How much more do you have to go?

22 MS. BROWN:

23 About five or ten minutes.

24 MS. O'DELL:

1 If you need a break, we can break now.

2 Or we can keep -- if you would like to wait five
3 or ten minutes, that's fine. Whatever's best for
4 you, Doctor.

5 THE WITNESS:

6 Yeah, if we could break now, that would
7 be great.

8 VIDEOGRAPHER:

9 Going off the record. The time is
10 2:10 p.m.

11 (OFF THE RECORD.)

12 VIDEOGRAPHER:

13 We're back on the record. The time is
14 2:26 p.m.

15 MS. BROWN:

16 Q Welcome back, Doctor.

17 Before we took a break, we were
18 discussing the Penninkilampi article. Do you
19 remember that?

20 A I do.

21 Q And one of the things the authors of
22 this very recent meta-analysis discussed is the
23 potential mechanism of ovarian cancer. Correct?

24 And I'll direct your attention to the

1 discussion that begins on page 45. In the second
2 sentence, the authors conclude here that the
3 mechanism by which perineal talc use may increase
4 the risk of ovarian cancer is uncertain.

5 Do you see that?

6 A I see that sentence, yes.

7 Q And they go on to discuss the theory
8 that talc could produce a chronic inflammatory
9 response which could predispose to the
10 development of ovarian cancer.

11 Do you see that?

12 A Yes.

13 Q Okay. And they go on to explain a
14 little bit more about the theory. Do you see
15 that?

16 MS. O'DELL:

17 Object to the form.

18 A Specifically the sentence beginning
19 with "it is argued"?

20 MS. BROWN:

21 Q Uh-huh. "It is argued that cellular
22 injury, oxidative stress, and local increase in
23 inflammatory mediators such as cytokines,
24 prostaglandins may be mutagenic and, hence,

1 promote carcinogenesis."

2 Do you see that?

3 A I see that.

4 Q This sentence refers to chronic
5 inflammation promoting cancer. Correct?

6 MS. O'DELL:

7 Object to the form.

8 A No. This -- this refers to that the
9 presence of -- proposed that talc as a
10 foreign -- that the presence of a foreign body
11 would instigate a chronic inflammatory response.
12 That's the statement in the paper.

13 MS. BROWN:

14 Q Is it your opinion that talcum powder
15 can cause chronic inflammation that initiates
16 cancer?

17 A It's -- so it is -- it is my opinion
18 is, part of the mechanism, that talcum powder can
19 have two effects related to inflammation. The
20 first effect is an acute effect resulting in
21 cellular damage, and that is supported by the
22 study showing increase in reactive oxygen species
23 related to talc.

24 The -- beyond that, the continued

1 presence of the talc or a continued chronic
2 immune response or chronic inflammatory response,
3 again, either directly or indirectly related to
4 the exposure, would help support a environment
5 that would allow the cancer progression to occur.

6 So that is simply delineating those --
7 those two things as it relates to inflammation
8 and talc exposure.

9 Q So you described two potential
10 responses to talc right now. Correct?

11 MS. O'DELL:

12 Objection to form.

13 A At least two, yes.

14 MS. BROWN:

15 Q Okay. And one is an acute inflammatory
16 response; correct?

17 A Yes.

18 Q And for that you point to the Saed data
19 on reactive oxygen species; is that right?

20 MS. O'DELL:

21 Objection to form.

22 A That is one example, yes.

23 MS. BROWN:

24 Q Okay. Are there -- is there other

1 scientific support for your opinion that talc can
2 cause acute inflammation?

3 A So it's any of the similar studies to
4 Saed. And I would have to double-check the
5 references, but they would have -- you know, any
6 of the --

7 MS. O'DELL:

8 Feel free to --

9 MS. BROWN:

10 Q Buz'Zard?

11 A So Buz'Zard would be one. Harper and
12 Saed is -- is another.

13 Q In your --

14 A And so -- yeah. Yes, Buz'Zard and Lau
15 and then -- yeah. So that would --

16 Q Okay. So for your opinion that talc
17 causes an acute inflamm- -- inflammatory
18 response, you rely on the cell studies done by
19 Saed and Buz'Zard; correct?

20 MS. O'DELL:

21 Object to the form.

22 A Yes, among others.

23 MS. BROWN:

24 Q In your opinion, Doctor, does that

1 acute inflammatory response resolve?

2 A I don't -- I don't have any evidence to
3 suggest it resolves or not. The --

4 Again, getting back to the mechanism
5 that has been -- that I've described and is
6 supported by the literature we've been discussing
7 is that there is a acute response as well as
8 evidence for talc causing a more chronic
9 inflammatory response. And so I've proposed a
10 mechanism by which both of those can contribute
11 to or enhance the development of cancer.

12 Q Can both of those inflammatory
13 responses that you just described initiate
14 cancer?

15 MS. O'DELL:

16 Object to the form. Asked and
17 answered.

18 A They are certainly a component of that.

19 And so, again, to restate the
20 mechanism, the acute inflammatory response or
21 the -- the formation of reactive oxygen species
22 has been known for decades to cause cellular
23 damage, and then cellular damage can result in
24 mutation of -- of DNA.

1 And then when you also consider the
2 full constituents of the products, the potential
3 presence --

4 And this gets back to our earlier
5 discussions about amplification.

6 Components such as chromium, which have
7 a direct DNA-damaging effect, can also
8 ampli- -- again, add to the level of cellular
9 damage present.

10 And then the continued inflammatory
11 response, whether it is a -- related to the
12 initial acute response and a continuation of that
13 or is a separate chronic inflammatory response
14 would then support the environment necessary for
15 the malignant transformation or the malignancy of
16 the cancer to become what we -- what we would
17 generally refer to as ovarian cancer.

18 Q In your opinion, the chronic
19 inflammation promotes the cancer but does not
20 initiate it?

21 MS. O'DELL:

22 Object to the form. Asked and
23 answered.

24 A No. So I wouldn't -- I would say

1 they're not -- I don't have evidence to -- to
2 delineate those specifically, other than -- other
3 than the supported mechanism that an acute
4 response can cause cellular damage, and then a
5 chronic response can cause cellular damage and be
6 supportive of that continued -- that continued
7 transformation.

8 So they are -- they -- those -- those
9 two delineated immune responses can either work
10 in -- in concert with each other, but there is no
11 evidence to suggest that one is insufficient
12 relative to the other in terms of progression of
13 the disease.

14 And I think specific to the -- to the
15 supported mechanism is that there -- I'm not
16 making that distinction in the -- in the report.
17 MS. BROWN:

18 Q Right. In your report, you don't talk
19 about acute versus chronic inflammation.
20 Correct?

21 A That's correct. I don't delineate the
22 two. Right.

23 Q But, here today, as we discuss in more
24 detail your opinions, you're explaining that

1 you're -- in your mind, you see two potential
2 inflammatory responses from talc. Right?

3 MS. O'DELL:

4 Object to the form.

5 A I would disagree. I would say that
6 I -- I -- based on the information and studies,
7 the -- the review of other expert reports, that
8 it presents a supported opinion that talc has an
9 ability to cause an acute response as well as a
10 chronic response.

11 And, so, then, today we are discussing
12 using that data in support of the -- of the
13 mechanism as to how those -- those two responses
14 can work together or separately in the
15 progression of ovarian cancer.

16 MS. BROWN:

17 Q At the time you wrote your report in
18 November of 2018, were you of the view that talc
19 can cause both acute and chronic inflammatory
20 response?

21 A Yes. I mean, it was -- I was of the
22 view it causes an inflammatory response. And
23 then, as I continued to review information
24 available, it became clear that the talc

1 response, being an inflammatory response in
2 totality, may have the ability to have
3 those -- to -- to have two independent responses
4 in tissues.

5 Q And, in your opinion, can both the
6 acute inflammatory response and the chronic
7 inflammatory response separately cause ovarian
8 cancer?

9 A Under the -- the mechanism I've
10 proposed, yes, that would be a -- a possibility
11 that they could separately cause, given that
12 they -- they're both inflammatory responses, they
13 both cause cellular damage.

14 And in the case -- in this case,
15 delineating the acute from chronic was more to
16 clarify the cellular damage aspect, the
17 transformative aspect of cancer from the -- the
18 necessary tumor progression aspects of cancer to
19 actually progress to disease.

20 Q In your opinion, Doctor, does talc
21 always first cause an acute reaction and then a
22 chronic reaction?

23 MS. O'DELL:

24 Object to the form.

1 A I -- I -- I don't have evidence
2 to -- to state that and would defer to some of
3 the other expert witnesses, like Dr. Saed, for
4 opinions on acute response versus chronic.

5 MS. BROWN:

6 Q In your opinion, though, you have at
7 least delineated in your mind two different types
8 of inflammatory responses. Correct?

9 MS. O'DELL:

10 Objection to form.

11 A I've -- I have described two mechanisms
12 for inflammation that -- that both can -- are
13 both supportive of the overall mechanism that
14 we're discussing.

15 MS. BROWN:

16 Q And is it -- is there a length of time
17 that differentiates an acute inflammatory
18 response from a chronic inflammatory response?

19 A Certainly I would say there -- in my
20 opinion, there would -- it would be a potential
21 time dependency or a magnitude dependency to
22 delineate an acute versus chronic response. But,
23 again, for the purpose of the biological
24 mechanism, separating them on those lines is not

1 important.

2 Q So there is a length of time or an
3 amount of exposure that would cause a chronic
4 inflammation that is different from the length of
5 time and the magnitude of exposure that will
6 cause an acute inflammation?

7 MS. O'DELL:

8 Object to the form. Misstates his
9 testimony.

10 A Yeah, no. Not -- that's not what
11 I -- that's not what I've stated.

12 I've simply stated that if we -- if we
13 look at the -- what is known about inflammation
14 and the biological response to foreign bodies,
15 you can have an initial acute response mediated
16 by the immune system and mediated by some of the
17 cellular damage that takes place, and then that
18 same response may continue in a chronic form for
19 some period of time and at some level of
20 magnitude.

21 Now, certainly there is likely a
22 dependency or, I should say, likely a
23 relationship to the amount of exposure and the
24 magnitude of that response.

1 But, again, the -- the opinions here
2 are specific to the mechanism and the initial
3 elucidation of that response and, you know,
4 not -- not on a quantitation of a -- a
5 dose-response relation -- or a dose-response
6 curve or relationship.

7 MS. BROWN:

8 Q Do you believe that every time a talc
9 particle enters the human body, it produces a
10 inflammatory response?

11 A All of the evidence would suggest yes.

12 Q Have you considered Heller's 1996 study
13 on that score?

14 A I would have to --
15 On the score of inflammatory response?

16 Q Do you recall that Heller looked at
17 benign ovarian tissue and identified the
18 potential presence of talc?

19 A Sounds familiar.

20 Q I'll hand it to you.

21 (DEPOSITION EXHIBIT NUMBER 19
22 WAS MARKED FOR IDENTIFICATION.)

23 MS. BROWN:

24 Q Handing you, Doctor, what we've marked

1 Heller's '96 article as Exhibit 19.

2 And what I want to ask you about is
3 Heller's finding as it relates to no reaction to
4 the talc particle. Did you consider that --

5 MS. O'DELL:

6 Object to the form.

7 MS. BROWN:

8 Q -- in forming your opinion here?

9 MS. O'DELL:

10 Excuse me. Object to the form.

11 MS. BROWN:

12 Q I'll direct you, Doctor.

13 On page 1508 of the Heller article,
14 right above the comments section, "The
15 investigators on this study concluded no evidence
16 or response to talc, such as foreign body giant
17 cell reactions or fibrosis in the tissue."

18 My question is whether, in your
19 opinion, every time talc is -- enters the body,
20 it necessarily produces an inflammatory response.

21 MS. O'DELL:

22 Object to the form.

23 A No. My opinion is that every time talc
24 enters the body, that has the potential to cause

1 an immune response.

2 MS. BROWN:

3 Q Have you made a determination about
4 whether or not that always happens?

5 A I'll have --

6 MS. O'DELL:

7 Object to the form. It's vague.

8 A I'm not aware of any --

9 There -- there -- these -- none of the
10 studies that have been reviewed have been
11 designed to answer the question of "if ever."

12 MS. BROWN:

13 Q So, in your view, then, it's an open
14 question about whether talc can be inside the
15 body and not produce an inflammatory response.

16 MS. O'DELL:

17 Object.

18 MS. BROWN:

19 Q Is that fair?

20 MS. O'DELL:

21 Excuse me. Objection to form.
22 Misstates his testimony.

23 A So my -- my -- my testimony regarding
24 the mechanism is that there is a well-supported

1 mechanism that talc causes inflammation and then
2 inflammation has a role in ovarian cancer.

3 Extending that to circumstances where
4 an exposure would not cause inflammation is -- is
5 not germane to that -- to that mechanism and, in
6 fact, again, not supported by literature to show
7 that, you know, that a single exposure or some
8 number of exposures are necessary or sufficient
9 for a particular phenotype.

10 MS. BROWN:

11 Q So this Heller study purports to have
12 found talc in ovarian tissue without an
13 inflammatory response; right?

14 MS. O'DELL:

15 Object to the form.

16 A In looking at their --

17 Just one moment.

18 So this was a --

19 So is your -- is your question that
20 the -- if the -- if the author showed talc being
21 present in normal ovarian tissue?

22 Q Well, first my question is did you
23 consider this article in connection with your
24 opinions in the case?

1 A I don't recall this article
2 specifically, and I don't believe I cited it.

3 I guess there's -- no.

4 Q And then my second question, Doctor, is
5 is it your opinion that every time the human body
6 is exposed to particles of talc, it necessarily
7 produces an inflammatory response that can either
8 promote or initiate cancer of the ovaries?

9 MS. O'DELL:

10 Object to the form.

11 A No. My --

12 MS. O'DELL:

13 Vague.

14 A My comment was that the -- that any
15 exposure to talc, particularly the perineal
16 exposure to talc, has the potential to cause an
17 inflammatory reaction.

18 I don't have any evidence that all of
19 the studies that we've been reviewing are in
20 support -- are in support of that mechanism, but
21 I don't know of a study that perhaps has been
22 able to draw a conclusion, from a similar size
23 study, to show that you can get significant talc
24 accumulation without an inflammatory response.

1 MS. BROWN:

2 Q Do you think you need significant talc
3 accumulation in the human body to cause or
4 promote ovarian cancer?

5 MS. O'DELL:

6 Objection to form.

7 A I wasn't asked to -- to provide --
8 provide that opinion.

9 And, again, referring to the studies
10 that have -- that were reviewed and included in
11 the report, there is a relationship between
12 lifetime exposure and an increased risk in the
13 epidemiology reports.

14 But more detail on that in this
15 discussion, I would defer to the epidemiology
16 experts. But the -- there -- there does appear
17 to be a -- more of a response based on more talc
18 in the -- in the studies referenced.

19 MS. BROWN:

20 Q So on --

21 Do you have any reason to dispute the
22 findings of Heller here of talc in the ovaries
23 without a foreign body reaction?

24 MS. O'DELL:

1 Objection.

2 A I guess my -- I have some -- I guess I
3 have some concerns with some of the methodology
4 as it relates to the detection of the...

5 MS. BROWN:

6 Q Do you think it's possible, Doctor, for
7 talc to enter the body and -- and be completely
8 inert and not cause any reaction?

9 MS. O'DELL:

10 Object to the form.

11 A So my -- the -- the mechanism I've
12 proposed is -- is based -- you know, based on the
13 literature, is that talc causes an inflammatory
14 response and that inflammatory response is
15 supportive of progression to ovarian cancer.

16 MS. BROWN:

17 Q Does that happen 100 percent of the
18 time?

19 MS. O'DELL:

20 Object to the form. In terms of
21 inflammatory response or in terms of cancer?

22 MS. BROWN:

23 Q If you don't understand the question,
24 you'll let me know.

1 A In -- in terms of cancer, the
2 epidemiology would suggest -- or I would say
3 the -- the evidence in the literature is -- does
4 not allow that question to be answered, and the
5 reason being is when you look at the latency of
6 the disease and the progression of the disease
7 and the challenges in detecting it, there just
8 has not been enough time with the, perhaps, rigor
9 of analysis that is undergoing now to make that
10 assessment of is it 100 percent of the time or is
11 it something less than 100 percent of the time.

12 I think, statistically speaking,
13 there -- the only data that -- that is available
14 for review is -- is what is contained in some of
15 the meta-analysis and epidemiology studies
16 showing a significant increased risk to ovarian
17 cancer based on exposure to talc. And it
18 would -- it would only be -- I think it would be
19 inappropriate at this time to try to infer what
20 percentage of time that would be indicative of
21 for exposure.

22 Q Have the plaintiffs' lawyers shared
23 with you expert reports from their expert
24 pathologists who have looked at ovarian tissue of

1 plaintiffs in this litigation, purported to find
2 talc with no foreign body reaction?

3 MS. O'DELL:

4 Objection. There have been no
5 case-specific pathology reports disclosed in the
6 litigation we're here about today. And if
7 there's something else you're talking about, you
8 should be specific.

9 A The -- I don't recall a pathology
10 report. I've seen expert reports from
11 epidemiologists, OB-GYN and -- and some -- and
12 other scientists. But I don't recall a specific
13 pathology report.

14 MS. BROWN:

15 Q If the biologically plausible mechanism
16 that you posit in your report is true, would you
17 expect that the pathology slides of women with
18 ovarian cancer who have used talc would evidence
19 talcum powder with a foreign body reaction?

20 MS. O'DELL:

21 Object to the form. Incomplete
22 hypothetical.

23 A That, I would have to ask how you're
24 defining a foreign body reaction.

1 MS. BROWN:

2 Q Well, would you expect to see some
3 evidence of inflammation in the ovarian tissue of
4 women who used talcum powder products?

5 MS. O'DELL:

6 Object to the form. Incomplete
7 hypothetical.

8 A Overall, speaking to, as we were
9 discussing earlier, the potential for that
10 inflammatory response remains. But given the
11 heterogeneity in individuals, their overall
12 health, their natural variation in the levels of
13 activities of antioxidants, et cetera, I -- I
14 would state that I would expect a variety of
15 magnitude of response to a foreign body like talc
16 among the individuals exposed to it.

17 MS. BROWN:

18 Q You'd expect to see something; right?

19 MS. O'DELL:

20 Object to the form.

21 A No, not necessarily, because it -- it
22 very much depends on the timing that's -- that is
23 observed, how -- what methodology is used to
24 detect the presence of talc or detect the

1 presence of the inflammatory response, if it's,
2 you know, done histopathologically, if it is
3 based on a reactive oxygen species assay.

4 So given the -- speaking in general
5 terms, I think it's just inappropriate to make a
6 conclusion as to that, yes, you would always
7 expect to see something.

8 I would -- again, to restate what was
9 stated earlier, any -- any exposure has the
10 potential to cause that inflammatory response,
11 and then the time, scale, and magnitude of that
12 response is going to vary by person. Therefore,
13 I would expect there would be a variability in
14 individuals exposed to talc.

15 MS. BROWN:

16 Q Uh-huh. Is your opinion related to all
17 the different histologic types of epithelial
18 ovarian cancer?

19 A My -- my opinion is not exclusive to
20 any -- any one type. Certainly, the epithelial
21 serous being the more common and most virulent
22 type of cancers I think represents the most
23 common.

24 From a mechanistic perspective, I

1 mentioned some of the other subtypes and the
2 common gene mutations that go along with them and
3 as, again, supportive of the same mechanism. And
4 I think, if anything, the -- the current data
5 would suggest a -- a higher prevalence of a
6 particular subtype of cancer but certainly not
7 the -- the mechanism doesn't -- is not exclusive
8 to any one type.

9 Q In your view, all types of epithelial
10 ovarian cancer can be caused by inflammation?

11 A No. That's -- that's not my statement.
12 I would say all types of ovarian cancer are
13 supported by an inflammatory response but that,
14 as from a causative perspective, that's not what
15 the mechanism is provided as an opinion as to
16 cause. It's more that the -- an inflammatory
17 response plays a role in disease initiation
18 and/or progression.

19 Q In your view, Dr. Levy, it is
20 biologically plausible for inflammation to cause
21 all types of epithelial ovarian cancer; true?

22 A Again, I'm not -- I've not been
23 speaking to inflammation as a causative -- as a
24 cause of ovarian cancer. It is a factor in --

1 in -- in disease progression.

2 Q So when you conclude, as you do in your
3 report, that talcum powder products cause chronic
4 inflammation, you do not conclude that that
5 chronic inflammation causes ovarian cancer?

6 MS. O'DELL:

7 Object to the form.

8 A I wasn't asked to provide a causation.

9 MS. BROWN:

10 Q Your opinion here is limited to the
11 potential for talcum powder products to produce
12 inflammation; correct?

13 MS. O'DELL:

14 Object to the form.

15 A No. My -- so my opinion is a -- is a
16 supported plausible biological mechanism by which
17 the exposure to talc can lead to ovarian cancer.
18 And, in my opinion, as supported in the -- in the
19 report, that is through an inflammatory response.

20 MS. BROWN:

21 Q I must be missing you, Doctor. So are
22 you of the opinion that inflammation can cause
23 ovarian cancer?

24 A I'm of the opinion that inflammation is

1 a component of ovarian cancer.

2 Q Well, I'm not sure what you mean by
3 that. Can inflammation cause ovarian cancer?

4 MS. O'DELL:

5 Object to the form. Asked and
6 answered.

7 A I'm asked -- I suppose -- again, the
8 opinion here is of a mechanistic opinion, not a
9 causation. I would defer to some of the
10 epidemiology experts to have opinions on
11 causation.

12 MS. BROWN:

13 Q You don't have an opinion on whether or
14 not inflammation can cause ovarian cancer?

15 MS. O'DELL:

16 Different question.

17 A Correct. That's a --

18 As we've been discussing, my opinions
19 are that inflammation is a component of ovarian
20 cancer and can be attributed to aspects, not
21 exclusively, but contributing to aspects of its
22 initiation and aspects of its progression. But I
23 did not say that ovarian cancer is caused by
24 inflammation.

1 MS. BROWN:

2 Q And what scientific support do you have
3 for your opinion that inflammation is a component
4 of ovarian cancer and can be attributed to
5 aspects of ovarian cancer, including its
6 initiation?

7 A So, again, the synthesis of the -- of
8 the papers we've been discussing, including Saed
9 and others, showing the reactive oxygen species
10 produced from talc. And, then, as far as
11 inflammation and its role in cancer, there
12 are -- and it's a fundamentally accepted aspect
13 of cancer biology that's been around for -- for
14 quite some time. And we mentioned earlier that
15 there's a variety of review articles, including
16 the ones we were comparing sentences to earlier
17 today, that describe that in great detail.

18 Q It's not generally accepted, though,
19 that ovarian cancer is caused by inflammation.
20 Fair?

21 MS. O'DELL:

22 Object to the form.

23 A I think there's a number of studies
24 that --

1 Well, first, we're -- I want to be
2 cautious with our use of the word "cause"
3 and -- because that's, as we've been discussing,
4 this is a -- it is -- it is not controversial
5 that ovarian cancer -- inflammation plays a role
6 in ovarian cancer and -- and, again, my opinion
7 is not towards causation.

8 MS. BROWN:

9 Q Well, I mean, tumors themselves elicit
10 inflammatory responses; right?

11 A What -- so what -- specifically, what
12 are you referring to?

13 Q Well, you talk about tumor-activated
14 macrophages in your report; right?

15 A Yes.

16 Q There is an inflammatory response
17 that's produced by the tumor itself; correct?

18 A Yes. There are -- there -- there --
19 there are absolutely cancer progression markers
20 that are associated with continued inflammation.

21 Q And that has nothing to do necessarily
22 with the events that cause the cancer. Right?

23 MS. O'DELL:

24 Object to the form.

1 A Well, so the -- we -- we would be going
2 down a slightly different road. And if
3 we're -- so cancer as a complex disorder, you
4 know, begins with an initiating event. But there
5 is -- there is absolutely tumor evolution from
6 that initial event through the progression of the
7 disease.

8 So to state that the -- in the initial
9 inflammatory response to the tumor is -- is not
10 causative to the continuation of the disease I
11 think would be incorrect.

12 MS. BROWN:

13 Q The Penninkilampi authors -- to
14 conclude our discussion here -- concluded that
15 the paragraph you were looking at with the
16 sentence "The potential mechanism by which
17 genital talc is associated with an increased risk
18 of ovarian cancer, hence, remains unclear," do
19 you see that?

20 A Yes.

21 Q And this meta-analysis was published in
22 January of 2018; correct?

23 A Correct.

24 Q And it is, in fact, cited in the

1 majority of the plaintiff expert reports in this
2 litigation. Did you see that?

3 MS. O'DELL:

4 Object to the form. If you know that.
5 Don't speculate.

6 MS. BROWN:

7 Q That's why I asked "Did you see that?"

8 A So I didn't specifically look at if
9 this was referenced. I -- I certainly referenced
10 it. But I would also point out another important
11 part of the -- of this same reference, a -- about
12 halfway down the following paragraph, beginning
13 with "If chronic inflammation due to ascending
14 foreign bodies is indeed the mechanism by which
15 talc use is associated with ovarian cancer risks,
16 then these results fit the picture."

17 So I think the authors were both
18 describing some things that remain unclear but
19 also offering some comments that are supportive
20 of our earlier discussions today on this
21 mechanism.

22 Q And your opinion here today, Doctor, is
23 limited to the potential mechanism; right?

24 MS. O'DELL:

1 Object to the form.

2 A So my -- my opinion is -- is -- is
3 regarding a biologically plausible mechanism.

4 But, then -- and, in doing so, have reviewed some
5 of these studies that we're discussing now.

6 MS. BROWN:

7 Q Good.

8 And, as it relates to that potential
9 mechanism, these Penninkilampi authors conclude
10 that the potential mechanism remains unclear.
11 Right?

12 MS. O'DELL:

13 Objection to form.

14 A They -- the article makes a statement,
15 "The potential mechanism by which genital talc is
16 associated with an increased risk of ovarian
17 cancer, hence, remains unclear."

18 However, as we've been discussing, they
19 go on to state, "If chronic inflammation due to
20 ascending foreign body is indeed the mechanism,"
21 then there -- the results in this paper
22 are -- fit that model.

23 So I think they're making reason- --
24 making reasonable statements based on the

1 available data that there is a biologically
2 plausible mechanism surrounding and, indeed, in
3 the previous paragraph at the end of it where
4 they discuss use of -- or expression of
5 cyclooxygenase 1 and 2 as well as the action of
6 NSAIDs, again, supportive of -- somewhat
7 supportive of the inflammatory model. But...

8 MS. BROWN:

9 Q Well, as it relates to the NSAIDs,
10 Doctor, they point to the fact that the NSAID
11 data is inconsistent, at best, as evidence
12 supportive of their conclusions that the
13 mechanism is unclear; right?

14 A No. They point to it as -- they
15 actually try to clarify that the -- the seemingly
16 contradictory data regarding the NSAID use can be
17 explained by the relatively low expression of
18 cyclooxygenase 1 and cyclooxygenase 2, which are
19 the targets of most common NSAIDs.

20 Q What they say is that the use of
21 nonsteroidal anti-inflammatory drugs, NSAIDs, is
22 not inversely associated with the incidence of
23 ovarian cancer as may be expected if the etiology
24 was related to chronic inflammation. Right?

1 MS. O'DELL:

2 Objection to form.

3 A Yes, that statement is made. But,
4 importantly, it is incomplete without the next
5 sentence, again, explaining that -- that
6 apparent -- that apparent question.

7 So if the -- if NSAIDs are not
8 effective in ovarian cancer and the -- and, in
9 turn -- and if the observation is also made that
10 ovarian cancer cells don't express cyclooxygenase
11 1 and 2, then they would not -- they would be
12 nonresponsive to NSAIDs.

13 Q You state on page 12 of your report,
14 Doctor, in the last paragraph, the second-to-last
15 sentence that begins "moreover," that the effect
16 of nonsteroidal anti-inflammatory drugs, NSAIDs,
17 to reduce the risk of ovarian cancer provides
18 additional support for what you're discussing
19 here, which is that chronic inflammation plays a
20 key role in the development of ovarian cancer.

21 Right?

22 A Correct.

23 Q And that is, in fact, the opposite of
24 what the authors in Penninkilampi report as

1 relates to NSAIDs; right?

2 MS. O'DELL:

3 Object to the form.

4 A Not -- not necessarily. So there's --
5 getting back to the -- the specific cells under
6 question and the inflammatory response being
7 examined. And, so, if we are lowering overall
8 chronic inflammation through the use of an NSAID
9 is -- is one question. A separate question is is
10 a -- is a ovarian cancer cell responsive to
11 NSAIDs. So they're two separate biological
12 phenomenon.

13 And, in one case, if those cells are
14 not expressing the cyclooxygenase 1 and 2,
15 they'll be nonresponsive.

16 I would speculate that NSAID use in the
17 rest of the body would still result in the
18 expected effect due to, you know, the -- due to
19 the inhibition of cyclooxygenase 1 and 2.

20 So I don't think they're necessarily in
21 conflict with each other.

22 (DEPOSITION EXHIBIT NUMBER 20

23 WAS MARKED FOR IDENTIFICATION.)

24 MS. BROWN:

1 Q Handing you what we've marked as
2 Defense Exhibit 20 to your deposition, this is a
3 paper by Merritt entitled "Talcum Powder Chronic
4 Pelvic Inflammation and NSAIDs in Relation to the
5 Risk of Epithelial Ovarian Cancer."

6 Do you see that?

7 A I do.

8 Q And, in fact, on page 12 of your
9 report, you cite this Merritt article. Correct?

10 A Yes. Uh-huh.

11 Q And you cite it for the proposition
12 that studies have found a relationship between
13 pelvic inflammatory disease and ovarian cancer
14 risk. Correct?

15 A Correct.

16 MS. O'DELL:

17 Object to the form.

18 MS. BROWN:

19 Q And you point to Merritt when you
20 determine here as a finding of a relationship
21 between pelvic inflammatory disease and ovarian
22 cancer in support of your opinion that
23 inflammation can cause ovarian cancer. True?

24 A I'd have to double-check that

1 statement.

2 And then there was, I think,
3 importantly, the Lin 2011 paper is also relevant.

4 Q Well, as it relates to the Merritt
5 paper, this cite is wrong; right?

6 A I need a moment to --

7 Q Let's look at what Merritt actually
8 found about pelvic inflammatory disease.

9 If you look --

10 MS. O'DELL:

11 If you need a moment --

12 Excuse me. I'm sorry. I didn't mean
13 to interrupt you.

14 If you need a moment to refresh
15 yourself, Dr. Levy, please do.

16 MS. BROWN:

17 Q Sure. And if you -- when you're ready,
18 Doctor, I'll direct you to the second column on
19 page 174, and I want to talk about the last
20 paragraph there that begins "if inflammation."

21 A Page?

22 Q And I'll read it into the record while
23 you orient yourself. It's page 174, right-hand
24 column. Final paragraph states, "If inflammation

1 plays a role in the etiology of ovarian cancer,
2 then it would be expected that PID would be
3 associated with increased risks of ovarian
4 cancer. PID is not associated with elevated risk
5 of ovarian tumors in our data, confirming several
6 previous reports of no association with PID in
7 studies of all subtypes of ovarian cancer."

8 Did I read that correctly?

9 A You did.

10 Q All right. So you cited this study for
11 the proposition that studies have found a
12 relationship between PID and ovarian cancer risk.
13 Right?

14 A No. I said -- I cited -- I said
15 studies have found a relationship, yes, between
16 PID and ovarian cancer risk.

17 Q And, in fact, this study did not find a
18 relationship between PID and ovarian cancer risk.
19 Right?

20 A I think this study found a -- I'm just
21 looking at the...

22 So -- I'm sorry. Would you ask your
23 question again? This -- this study did not
24 find your --

1 Yes, I --

2 Q Sure. I just -- you cited this study
3 for the proposition that it showed there was a
4 relationship between pelvic inflammatory disease
5 and ovarian cancer risk, but, in fact, the study
6 showed the opposite. Correct?

7 A Well, to be clear on the wording,
8 stated that the studies have found a
9 relationship. I didn't indicate whether it was
10 positive or negative.

11 But I think, importantly, the study
12 also has an important paragraph that is probably
13 more related to its inclusion, which is on the
14 same page we were just on, 174, second full
15 paragraph in the discussion.

16 Q One of the things on this page,
17 Doctor --

18 MS. O'DELL:

19 Are you finished, Doctor?

20 A I think important to at least finish
21 that thought.

22 That paragraph reads, "Focusing on talc
23 use, we found that any use of perineal talc was
24 associated with a small but significantly

1 increased risk of ovarian cancer overall and
2 specifically amongst the invasive and LNP serous
3 tumors, although no clear dose response with
4 increase in duration of use was identified. This
5 finding is consistent with results of previous
6 studies."

7 So in the case of the report and the
8 biologically plausible mechanism that's been
9 supported by these studies, these studies
10 differentiating the process of pelvic
11 inflammatory disease doesn't ex- -- doesn't
12 exclude or refute the inflammatory role or the
13 role inflammation may play in ovarian cancer.

14 Q What this study concludes is that, on
15 balance, chronic inflammation does not play a
16 major role in the development of ovarian cancer.
17 Do you recall reviewing this in connection with
18 your opinions in this case?

19 MS. O'DELL:

20 Object to the form. Misstates the
21 exhibit.

22 MS. BROWN:

23 Counsel, I'll direct you to the last
24 paragraph of the abstract on page 1 which reads,

1 quote, "We conclude that, on balance, chronic
2 inflammation does not play a major role in the
3 development of ovarian cancer."

4 Q Do you see that, Doctor?

5 A I see that.

6 Q And what this study did was it
7 endeavored to look into factors potentially
8 associated with ovarian inflammation to see if it
9 could support the theory that chronic
10 inflammation plays a role in ovarian cancer;
11 right?

12 MS. O'DELL:

13 Object to the form.

14 A I would need to -- this one limitation
15 of this particular paper is that it is connecting
16 inflammation as evidenced by pelvic inflammatory
17 disease and assuming that that source and type of
18 inflammation would be -- the fact that there's
19 not a direct association between -- or an
20 increased risk of ovarian cancer in the presence
21 of pelvic inflammatory disease; therefore,
22 inflammation must not play a role in ovarian
23 cancer. So that is their conclusions.

24 MS. BROWN:

1 Q Well, they looked at a bunch of
2 different inflammatory conditions, didn't they?
3 That was the focus of the study. The authors
4 endeavored to look at a number of different
5 pro-inflammatory factors and see if they
6 influenced ovarian cancer. Do you recall
7 reviewing that?

8 A I do. I think -- but, more
9 importantly, when we look at the -- their
10 specific statements that are surrounding the
11 mechanism we're discussing today, which has to do
12 with talc exposure and perineal talc use, I think
13 their -- their statements in that sense, which
14 have already been read, quite stand on their own.

15 So what this may indicate is a variety
16 of types of inflammation do -- as present in
17 other diseases, those individually do not or may
18 not have a specific role in the progression of
19 ovarian cancer.

20 But it does not -- again, it does not
21 mean that ovarian inflammation at the site of
22 talc exposure in the ovary can't have a role in
23 the progression of disease where -- again, as we
24 were discussing earlier, with inflammation, we're

1 now connecting independent biological processes.

2 And I think you're -- I want to be sure
3 we're clear and not drawing the use of the word
4 "chronic inflammation" as meaning any
5 inflammation and, therefore, if it's not
6 associated with ovarian cancer, that inflammation
7 can't have a role.

8 What we're speaking about in terms of
9 this mechanism is inflammation caused by the
10 perineal use of talcum powder in the ovary and
11 the -- and the -- to explain that increased risk
12 of ovarian cancer, what is a plausible mechanism.

13 Q The authors write, on page 74 -- 174,
14 Doctor, second column, paragraph that begins with
15 "It has been hypothesized," "It has been
16 hypothesized that talc is linked to ovarian
17 cancer development through inflammation," comma,
18 "however evidence linking an inflammatory
19 response with talc contamination of the ovaries
20 is lacking."

21 Do you see that?

22 A I do.

23 Q And you disagree with that statement?

24 A I would -- I would suggest that a

1 number of studies in the literature since the
2 publication of this paper would -- would suggest
3 that these conclusions may have been premature.

4 Q Do you think that, at the time this
5 paper was published in 2008, that Merritt was
6 accurately representing the data as it related to
7 whether chronic inflammation could play a role in
8 the development of ovarian cancer?

9 MS. O'DELL:

10 Object to the form.

11 A I would say that Merritt has an
12 unresolved -- has a number of unresolved
13 conclusions or partial conclusions in their
14 paper, again, including the paragraph we've
15 discussed where they comment on the talc use with
16 an increased risk of ovarian cancer.

17 MS. BROWN:

18 Q Did you see the confidence interval on
19 that finding, Doctor?

20 A I'd have to -- in --

21 Is this in this paper or in the number
22 of the --

23 Q You reference the finding of an
24 association between talc use and ovarian cancer a

1 couple times, and that's a 1.17 relative risk
2 that you're referring to. Is that right?

3 A Where is that?

4 Q I'm looking at -- in the abstract.

5 A Yes.

6 Q Right. And the confidence interval is
7 1.01 to 1.36. Right?

8 A Correct.

9 MS. O'DELL:

10 As to what finding?

11 MS. BROWN:

12 The one we're discussing.

13 Q And, Doctor, you know that one -- a
14 confidence interval that begins with one is not
15 statistically significant?

16 MS. O'DELL:

17 Object to the form.

18 MS. BROWN:

19 Q Did you know that?

20 MS. O'DELL:

21 Object to the form.

22 A Well, I would say the authors have
23 stated in that abstract that it is statistically
24 significant.

1 MS. BROWN:

2 Q Sure, because it's 1.01. My question
3 to you was do you know that a confidence interval
4 that begins with one is not statistically
5 significant?

6 This finding, Doctor, is barely
7 statistically significant, isn't it?

8 MS. O'DELL:

9 Object to the form.

10 A Again -- again, it's a -- whether it's
11 barely or whether it's tremendously statistically
12 significant, it -- it's still a finding that I
13 would say is in support of -- has been supported
14 by other studies with similar relative risk
15 numbers in the -- in the 1.2 range and above, as
16 indicated.

17 MS. BROWN:

18 Q Finally, Doctor, at the very -- the
19 very last sentence of this Merritt study we're
20 discussing, on page 175, concludes, "However,
21 experimental evidence that perineal talc use
22 elicits an inflammatory response in the ovaries
23 is lacking, and overall we conclude that chronic
24 inflammation does not play a major role in the

1 development of ovarian cancer."

2 And my question for you is what
3 methodology did you employ to consider the
4 findings of the Merritt paper in coming to your
5 opinions contained in your report?

6 MS. O'DELL:

7 Object to the form.

8 A Again, as we've discussed earlier here
9 today, the -- there's been no singular paper that
10 had a specific role in -- in developing the
11 biologically plausible mechanism contained in the
12 report. And, so, this -- this paper, among many
13 others, was -- was used.

14 MS. BROWN:

15 Q Right. But the findings of this paper
16 is that talcum powder doesn't produce an
17 inflammatory response that leads to cancer.
18 Right?

19 A The -- the findings of this paper was
20 that there's not an association of pelvic
21 inflammatory disease and risk of ovar- -- of
22 epithelial ovarian cancer.

23 Q They conclude that chronic inflammation
24 doesn't play a role in the development of ovarian

1 cancer; right?

2 A I think they've -- they've extended
3 that observation regarding pelvic inflammatory
4 disease to that conclusion.

5 But I think the studies that have come
6 after this and other -- certainly other areas of
7 review would suggest that those specific -- the
8 wording of those specific statements may not be
9 the most appropriate representation of the -- of
10 the observations made in the -- in the Merritt
11 paper.

12 Q So did you weight the Merritt paper
13 less than some other papers that came after it?
14 Or how did you --

15 What I'm trying to understand is your
16 methodology for considering this paper, which
17 seems to squarely conclude talc doesn't cause
18 inflammation.

19 MS. O'DELL:

20 Object to the form.

21 A I'm not -- so I would -- I would
22 disagree that -- this paper does not make those
23 conclusions that talc does not cause
24 inflammation. What they --

1 Again, the observations in this paper
2 are regarding chronic inflammation and its -- and
3 its major role in the development of ovarian
4 cancer; and, again, in this -- in the specific
5 individuals that they've looked at, it's in
6 regards to pelvic inflammatory disease.

7 And, so, as far as weighting that
8 paper, it would be similar to other papers and
9 other observations in the sense that it was --
10 that the mechanism that is supported by a wide
11 variety of work considers a history of -- history
12 of work in the talc, inflammation, and ovarian
13 cancer fields both in basic research and
14 epidemiology to come up -- to come to the
15 conclusions and mechanisms that are proposed.

16 I don't -- I can't give you a specific
17 weighting algorithm that was used on any -- any
18 given paper.

19 MS. BROWN:

20 Q Did you consider Merritt's finding that
21 evidence linking an inflammatory response with
22 talc of the ovaries is lacking?

23 A I certainly considered their -- I
24 considered their statements in the -- in the

1 paper. And I would question the dichotomy of
2 the -- of some of their statements regarding talc
3 risk to cancer.

4 And the first question that would come
5 to mind for this particular study is how they
6 assessed talc-related inflammation in --
7 specifically in the ovary. I don't recall seeing
8 how they made that assessment.

9 It, instead, seemed to me that their
10 assessments were based on chronic inflammation as
11 it related to other biological conditions and
12 then extrapolating that to rate of ovarian
13 cancer.

14 Q How do you think one should measure
15 talc-related inflammation in the ovary?

16 MS. O'DELL:

17 Object to the form.

18 A Again, I wasn't asked to -- to provide
19 that opinion. But I would reference the more
20 recent Saed paper which -- and other molecular --
21 and other molecular studies and certainly defer
22 to Dr. Saed as an expert witness to discuss
23 appropriate measurements for talc-related
24 inflammation in the -- in the ovary or ovarian

1 cells.

2 MS. BROWN:

3 Q Have you spoken with Dr. Saed?

4 A I have not.

5 Q Have you requested any information from

6 Dr. Saed?

7 A No, I have not.

8 Q Have you -- would you hold to the same

9 opinion if you did not consider the work of

10 Dr. Saed?

11 MS. O'DELL:

12 Objection to form. Vague.

13 A I -- the work of Dr. Saed is -- is a

14 consideration among the wide variety of other

15 literature contained in here. And Dr. Saed's

16 work for in vitro analysis and the quantitation

17 of specific reactive oxygen species is -- is a

18 factor in and it is in support of the mechanism

19 that I've proposed, which is that that mechanism

20 does not rely on that study or any singular study

21 for it to be valid.

22 MS. BROWN:

23 Q The mechanism you proposed, Doctor, is

24 not yet generally accepted in the scientific

1 community. Would you agree?

2 MS. O'DELL:

3 Object to the form.

4 A I wouldn't have a basis for that
5 opinion. As -- as we talked about earlier, I
6 haven't shared this mechanism to ask for that
7 opinion.

8 MS. BROWN:

9 Q You haven't published the proposed
10 mechanism that is the subject of your report. Is
11 that right?

12 A That's right.

13 Q You haven't discussed the proposed
14 mechanism that is the subject of your report with
15 any of your colleagues at HudsonAlpha; correct?

16 A That's correct.

17 Q So whether or not the proposed
18 mechanism that is the subject of your report
19 would be accepted by your peers in the scientific
20 community, that's not something you have yet
21 evaluated; correct?

22 MS. O'DELL:

23 Object to the form.

24 A My -- I wasn't requested to provide a

1 biologically plausible mechanism that was also
2 peer-reviewed, and I would rely on or point you
3 to a number of other expert reports, particularly
4 in the epidemiology space from this case, where
5 you'll find a great many parallels to -- to this
6 case.

7 So I, instead, would state
8 independently myself and other respected
9 scientists have essentially developed the same
10 opinions regarding mechanism in this -- in this
11 particular space.

12 MS. BROWN:

13 Q Is there another plaintiffs' expert
14 that you're aware of who holds the same opinion
15 as you do on biological plausibility?

16 A Yes.

17 Q Who's that?

18 A Patricia Moorman, who is an
19 epidemiologist whose report I had the opportunity
20 to read yesterday.

21 Q Is there -- and -- and even though
22 she's an epidemiologist, Dr. Moorman has a view
23 on biological plausibility? Is that right?

24 MS. O'DELL:

1 Object to the form.

2 A She has a view on --

3 In her report was a -- a view on
4 mechanism -- on mechanism, which included the
5 discussion of inflammatory response and its role
6 in ovarian cancer, which parallels this report.

7 MS. BROWN:

8 Q Do you consider your proposed mechanism
9 that is the subject of your report to be a novel
10 concept in the scientific world?

11 MS. O'DELL:

12 Object to the form.

13 A Which part?

14 MS. BROWN:

15 Q Any part.

16 MS. O'DELL:

17 Object to the form.

18 A Again, I -- my -- the -- what was
19 requested of me was not to develop a novel
20 concept or even to describe an untested
21 hypothesis. What was requested of me was to
22 review the available literature and provide a
23 biologically plausible mechanism for talc
24 exposure to ovarian cancer. And, so, that's

1 what -- that's what my report provides.

2 MS. BROWN:

3 Q Do you think there could be other
4 biologically plausible mechanisms by which talcum
5 powder would be associated with ovarian cancer?

6 A I haven't been asked to -- to make a
7 review related to other biological mechanisms. I
8 was asked to develop a biologically plausible
9 mechanism. And upon review of the totality of
10 the literature, this mechanism that -- that I've
11 presented and provided in the report is, in my
12 opinion, the correct mechanism.

13 Q Did you have complete autonomy in your
14 task to develop a biologically plausible
15 mechanism?

16 A Yes.

17 Q Were there any limitations on how you
18 should go about developing this biologically
19 plausible limita- -- mechanism?

20 MS. O'DELL:

21 Object to the form of the question to
22 the degree that the question seeks --

23 MS. BROWN:

24 Form.

1 MS. O'DELL:

2 No, no. If it goes to conversations
3 with counsel, it is not form. It is
4 attorney-client privilege and it's protected.
5 Work product privilege is protected.

6 And, so, Dr. Levy --

7 MS. BROWN:

8 No. Counsel --

9 MS. O'DELL:

10 Excuse me. Excuse me. I'm directing
11 my witness based on privilege, and I can do that.

12 To the degree that counsel is trying to
13 seek the substance of discussions you had with
14 counsel, those are protected, and I direct you
15 not to answer.

16 To the degree there's something in your
17 mind to respond that's not that, you may -- you
18 may respond.

19 MS. BROWN:

20 Q And as -- as counsel well knows,
21 because we've had this discussion earlier this
22 week, the federal rules allow discovery of any
23 material you relied on in forming your opinions.

24 And, so, my answer here -- my question

1 for you here, Doctor, is, were -- was there any
2 limitation placed on you that you relied on in
3 trying to develop your biologically plausible
4 mechanism?

5 MS. O'DELL:

6 What's allowed -- you're well aware of
7 this, counsel, I know -- that what's discoverable
8 is are there materials considered -- you can ask
9 him that -- was there assumptions that he was
10 asked to make -- that's discoverable -- and the
11 compensation. Those are the three things. Not
12 conversations between counsel and Dr. Levy.

13 So --

14 MS. BROWN:

15 Counsel, you can instruct or we'll get
16 the judge. We do not have time for your
17 speeches. We're trying to finish up and let
18 other people -- other people ask questions.

19 MS. O'DELL:

20 That's straight from the rules. You're
21 well aware of that.

22 MS. BROWN:

23 So here's the question. If you want to
24 instruct, we'll take a break and get the judge.

1 Q Did you rely on any instruction from
2 counsel regarding any limitations on how you were
3 to attempt to develop your biologically plausible
4 mechanism?

5 A No. I was -- I was not provided --
6 there were no --

7 I'm trying to make sure I answer to be
8 correct. But my very simple and direct answer is
9 the requests for the report were very succinct
10 and were given without limitation.

11 Q Did you try to develop any mechanism
12 that you rejected in connection with your report?
13 MS. O'DELL:

14 Object to the form. Vague.

15 A So I would best answer that by saying I
16 did not develop an initial mechanism and,
17 instead, began a literature review looking at the
18 available literature in talcum powder
19 inflammation in cancer, ovarian cancer, and then
20 in related subjects, and then, through the course
21 of that review, was able to synthesize the
22 opinion that you have, that we've been
23 discussing, in the report.

24 MS. BROWN:

1 Q Do you consider the biologically
2 plausible mechanism that is the subject of your
3 report to be a hypothesis?

4 MS. O'DELL:

5 Object to the form. Asked and
6 answered.

7 A No, no. In fact, it is not. And
8 it's -- I think it's very fundamentally different
9 than a hypothesis.

10 Because, again, to state, the
11 activities that were undertaken was a review of
12 the literature and then, based on that review, a
13 mechanism that was biologically plausible. It is
14 not hypothetical.

15 MS. BROWN:

16 Q Have you tested your biologically
17 plausible mechanism?

18 MS. O'DELL:

19 Object to the form.

20 A Tested in the sense of --

21 So I would -- I would answer that as --
22 in -- in my opinion, I would suggest that this
23 has been tested based on following the completion
24 of the report and reading other similarly derived

1 or similarly requested both literature, some of
2 the publications that we've been discussing, as
3 well as other expert reports that have, as we've
4 just discussed, some parallel aspects.

5 So, from a formal scientific process,
6 that is -- would not, I think, be considered a
7 formal test. But from the perspective of this
8 biologically plausible mechanism, other
9 scientists undertaking similar methodology came
10 up with similar results.

11 And, so, therefore, I would say that
12 this report is -- continues to be supported by
13 independent reviews and content.

14 MS. BROWN:

15 Q The other scientists that you just
16 referenced are also paid experts for the
17 plaintiffs; is that right?

18 MS. O'DELL:

19 Object to the form.

20 A I don't have knowledge of that
21 specifically.

22 MS. BROWN:

23 Q Well, when you said other experts
24 looking at the same thing came up with a similar

1 mechanism, you mean other experts in this
2 litigation?

3 MS. O'DELL:

4 Object to the form. Misstates his
5 testimony.

6 A Other -- other material -- the
7 materials that I was -- that I was provided.

8 MS. BROWN:

9 Q And those materials are in the form of
10 other expert reports like yours; right?

11 MS. O'DELL:

12 Object to the form.

13 A They are.

14 MS. BROWN:

15 Q Are you aware of any nonlitigation
16 expert that has arrived at the same biologically
17 plausible proposed mechanism as you?

18 MS. O'DELL:

19 Object to the form.

20 A Well, I think -- yeah, in the sense --
21 in the sense of the number of publications we've
22 been discussing and some of the more recent both
23 reviews and -- and Saed's paper, I suppose, as
24 we've been discussing, Dr. Saed has been funded

1 for some of this work, but I would counter that
2 with sponsorship of -- of studies that are
3 subsequently peer-reviewed, I think are generally
4 held to a scientific standard and rigor, and
5 would suggest that his most recent work would
6 fall under that and -- and, therefore, I would
7 not consider that in the same realm as an expert
8 report.

9 MS. BROWN:

10 Q Are you aware that the plaintiffs'
11 lawyers funded Dr. Saed's studies?

12 A I am.

13 Q How do you know that?

14 MS. O'DELL:

15 Don't speculate. If you know it,
16 testify to it.

17 A No. I'm thinking of --

18 That was disclosed during the
19 discussion of the -- of the paper, and the
20 question I asked and actually looked on the paper
21 was to --

22 And this -- this was getting to my own
23 opinion as to the appropriateness and the
24 potential scientific rigor of the paper, and that

1 was whether or not Dr. Saed disclosed that
2 relationship, which is, of course, ethically a
3 requirement for sponsored research. And, indeed,
4 that sponsorship is made in the paper.

5 MS. BROWN:

6 Q Was it important to you --

7 Did you ask Dr. Saed about the funding
8 for his paper?

9 A I did not. As we -- as we discussed, I
10 haven't spoken with him.

11 Q Were you troubled by the fact that
12 Dr. Saed's disclosure does not reference which
13 side of the litigation he's working for?

14 MS. O'DELL:

15 Object to the form.

16 A Are you asking for my opinion on if it
17 troubled me?

18 MS. BROWN:

19 Q Yeah.

20 A No.

21 Q It sounds like you did a little
22 investigation and you were satisfied with the
23 disclosure. Was that your testimony?

24 MS. O'DELL:

1 Object to the form. He didn't use the
2 word "investigation."

3 A I was satisfied seeing a disclosure
4 made regarding funding, which, again, in the
5 scientific climate I would -- or I would state
6 simply I viewed the support of that study which
7 subsequently goes out to peer review functionally
8 equivalent to pharmaceutical support of a study
9 involving a drug or a condition or a treatment.

10 The reality of the scientific space
11 is -- is -- is funding sponsorship comes from a
12 variety of cases. And in each institution,
13 HudsonAlpha certainly, I'm positive Wayne State
14 has a conflict of interest review board which
15 Dr. Saed has to report to as far as the -- how he
16 manages that potential conflict of interest. And
17 given that he's at a reputable institution that
18 I've actually done a fair amount of review work
19 with over the years, being Wayne State, I'm
20 reasonably -- or I would say I'm quite confident
21 that his conflict of interest has been managed
22 appropriately for the -- for the study that was
23 reviewed.

24 MS. BROWN:

1 Q Why is it important, in your mind, to
2 disclose funding for a study?

3 A Well, it's, you know, ethical premise
4 of -- of most scientific research or really all
5 extramurally funded research that the funding
6 sources are -- are always disclosed. And that's
7 true for publication as well as presentation.

8 And, so, I think most -- most
9 scientists, during presentation, will present a
10 slide that shows their -- their funding support
11 and all of its sources regard- -- whether it's
12 public or private.

13 And then you'll notice in vast majority
14 of publications, if they are grant supported,
15 again, whether that grant is from a public or a
16 private institution, those things are referenced.
17 And, in fact, the U. S. Government has a
18 requirement that grants be referenced in their --
19 in any publications that were supported by that
20 money.

21 Q Do you have any critiques of either of
22 Saed's papers?

23 A No. Not at this time.

24 Q Do you have any questions or anything

1 that doesn't make sense to you, having reviewed
2 the most recent one or the 2017 one?

3 A No. My focus, particularly on the most
4 recent one, I actually found his molecular
5 studies to be quite comprehensive and --

6 So there was -- there was no specific
7 concerns that -- that I was able to identify.

8 And, again, the -- in the -- in the version of
9 the paper that -- that I -- that I was given.

10 Q And did you have any opportunity to
11 check to see if you had an earlier version of
12 that paper?

13 A Oh, I -- I'll be sure and do that at
14 the next break.

15 Q Okay. Why don't we go ahead and take a
16 break now. You'll take a look, if you wouldn't
17 mind, to see if you have something other than
18 what we've marked at the deposition.

19 I'm going to renew -- review my notes.
20 I'm close to finishing, and then I'll hand it
21 over to my colleague, Mr. Ferguson, who I think
22 will have some questions for you as well. Okay,
23 Doctor?

24 A Uh-huh.

1 Q Thank you, Doctor.

2 VIDEOGRAPHER:

3 Going off the record. The time is 3:33
4 p.m.

5 (OFF THE RECORD.)

6 VIDEOGRAPHER:

7 We're back on the record. The time is
8 3:48 p.m.

9 MS. BROWN:

10 Q Welcome back, Doctor.

11 Did you have an opportunity to take a
12 look if you had an earlier version of Dr. Saed's
13 manuscript?

14 A I did.

15 I did not.

16 Q Okay. And, so, during this deposition,
17 you've referred from time to time to Dr. Saed's
18 2018 paper. Is that right?

19 A (Nods affirmatively.)

20 MS. O'DELL:

21 Object to the form. Excuse me.

22 MS. BROWN:

23 Q And you received that paper after you
24 authored your report in this case; right?

1 MS. O'DELL:

2 Object to the form.

3 A So I was referring --

4 Yes. I -- I -- the manuscript we were
5 discussing was received after the completion of
6 this. But, as we discussed earlier, the
7 materials in the paper were presented in abstract
8 form or long abstract form, and those are
9 referenced in the report.

10 MS. BROWN:

11 Q And just to close the loop on one thing
12 before I hand it over to my colleague,
13 Mr. Ferguson, you had referenced an animal study
14 by Woodruff earlier in the day. Do you remember
15 that?

16 A Yes.

17 Q That paper doesn't have anything to do
18 with talc; right?

19 MS. O'DELL:

20 Object to the form.

21 A Let me --

22 Yes, I -- you're -- the Woodruff 1979
23 paper is not the one I was -- I was wrong on the
24 author. Give me a moment to...

1 MS. BROWN:

2 Q And if that's not the one you were
3 thinking of, Doctor, we can move on.

4 A I was thinking Henderson 1971.

5 Q And that's not an animal study; right?

6 A Maybe this -- this isn't the same one,
7 then. I can certainly find it at the end if --

8 The -- it was a 1971 study involving a
9 rat model that the major point and conclusion of
10 the study was perhaps something that we've
11 discussed that's been now well accepted that the
12 talc can migrate, after exposure, into the
13 ovarian tissue.

14 Q Are you aware of any study, Doctor,
15 that talc on the exterior of a woman's vagina can
16 migrate up the fallopian tubes to the ovary?

17 MS. O'DELL:

18 Object to the form.

19 A I am not aware of a study that tested
20 that specifically.

21 MS. BROWN:

22 Q And did you consider, in connection
23 with your opinions here, IARC's finding that the
24 science regarding migration is, quote, "weak"?

1 MS. O'DELL:

2 Object to the form.

3 A My -- my primary consideration of IARC
4 was their classification of the talc and the --
5 and the fibrous talc, and I don't recall their
6 conclusions of the migration science being weak.

7 And, in fact, it appears, as stated by
8 the FDA, that the -- the migration question is --
9 is well resolved.

10 MS. BROWN:

11 Q Finally, Doctor, in connection with
12 your opinions in this case, did you consider
13 articles regarding whether stick lesions evidence
14 inflammation?

15 A I'd have to review some of the
16 literature for stick lesions specifically. But
17 that --

18 Can you -- what are you referring to by
19 stick lesions?

20 Q So do you understand that it's now
21 believed, in terms of the -- where ovarian cancer
22 begins, that it begins in the fallopian tubes,
23 epithelial ovarian cancer?

24 A I certainly would agree that a -- the

1 site of initiation, whether -- that it can begin
2 in the fallopian tubes, yes, that there's been
3 studies that have shown that evidence.

4 Q And some of the early lesions that have
5 been found in the fallopian tubes are sometimes
6 referred to as stick lesions. Are you familiar
7 with that?

8 MS. O'DELL:

9 Object to the form.

10 A I'm not.

11 MS. BROWN:

12 So you haven't looked at any studies
13 that have looked at stick lesions that have been
14 removed from women to see if there was any
15 evidence of inflammation?

16 MS. O'DELL:

17 Object to the form.

18 A That -- that -- I don't recall that as
19 part of the review.

20 MS. BROWN:

21 Q Fair enough.

22 No further questions. I'll hand it
23 over to Mr. Ferguson.

24 MR. FERGUSON:

1 Thank you.

2 EXAMINATION

3 BY MR. FERGUSON:

4 Q Good afternoon, Dr. Levy. My -- my
5 name is Ken Ferguson, and I represent Imerys in
6 this matter. Do you know who Imerys is?

7 A Only that they're a mining company.

8 Q Okay. And I have some questions for
9 you. I apologize for my voice. I've kind of had
10 my allergies and then going into a cold, so it's
11 kind of -- kind of stuffy. So I apologize.

12 If you have trouble hearing me or
13 understanding me, let me know. Okay?

14 A Okay.

15 Q And -- and just -- I know you've been
16 at this with Miss Brown for a little while, but
17 if there's any question that you don't understand
18 that I'm asking you, just let me know, and I'll
19 restate it so I can make sure that we're
20 communicating. Okay?

21 A Okay.

22 Q I want to talk to you, first of all,
23 about a little bit more about what you do at
24 HudsonAlpha Institute. So in the what's called

1 the Genomic Services Laboratory --

2 Right? There's one of those at
3 HudsonAlpha; right?

4 A There is.

5 Q Do you perform services there such as
6 running clinical samples to report results to
7 healthcare providers? Is that the kind of things
8 you do?

9 A To be -- to be clear and to,
10 importantly, differentiate the regulated lab
11 versus the research laboratory, the Genomic
12 Services Laboratory is a -- is a entity of
13 HudsonAlpha that is responsible for research
14 activities.

15 There is a separate wholly owned
16 subsidiary of HudsonAlpha creatively named the
17 Clinical Services Laboratory. So that laboratory
18 is the laboratory that performs the testing. And
19 to hopefully not provide a level of confusion,
20 but the two laboratories coexist in the same
21 space. And what this means is I have staff and
22 equipment. Some is dedicated to clinical, some
23 is dedicated to research, and some are shared
24 between the two.

1 So, in summary, the best way to
2 consider the laboratory is that it's a clinical
3 regulated laboratory that also performs research.

4 Any projects under that research
5 umbrella are referred to as being in the Genomic
6 Services Laboratory. Anything clinical is
7 referred to the Clinical Services Laboratory.
8 That lab has been CLIA-licensed now for going on
9 five -- just past four years and has been
10 CAP-accredited for three and a half.

11 Q So is it the Clinical Services
12 Laboratory, then, that would perform services
13 like running clinical samples to get results to
14 healthcare providers?

15 A That's correct.

16 Q And -- and among those things that the
17 Clinical Services Laboratory does, is that
18 restricted to whole genome sequencing?

19 A Our currently -- the only publicly
20 disclosed and validated test for the Clinical
21 Services Laboratory is whole genome sequencing.

22 We have two other laboratory-developed
23 tests, or commonly referred to as LDTs, that are
24 run in a -- as a private assay for some clinical

1 trials, so they're not publicly available and to
2 date have not been publicly disclosed. They're
3 protected under confidentiality agreement.

4 And the Clinical Services Laboratory
5 this year will launch a number of other tests
6 that we have publicly disclosed. Those include
7 whole exome sequencing, an oncology panel known
8 as the TruSight Tumor 170, which profiles 170
9 genes with -- that have been -- that have known
10 involvement in cancer risk and progression, and
11 as well as a 500 panel of similar form.

12 Q So let me talk to you a little bit
13 about your prior position. You were at
14 Vanderbilt University Medical Center; correct?

15 A Correct.

16 Q And you were an assistant professor?
17 Is that correct?

18 A The titles I held there was research
19 assistant professor and then assistant professor,
20 and then I was a associate professor as an
21 adjunct faculty for a number of years after
22 joining HudsonAlpha. So I had to progress
23 through a few of the academic ranks at
24 Vanderbilt, but all of them in the professor

1 realm.

2 Q As an assistant professor, were you
3 appointed on a tenure track?

4 A Yes.

5 Q And do you know generally how many
6 years after appointment as an assistant professor
7 is a tenure decision at Vanderbilt typically made
8 in that department?

9 A It varies from probably five to nine.

10 Q Did you ever achieve tenure at
11 Vanderbilt?

12 A Actually, I was up for tenure the year
13 that I moved to HudsonAlpha.

14 Q So --

15 A So, technically, I, which will sound
16 odd, I was promoted to associate professor upon
17 leaving.

18 Q Okay.

19 A In an adjunct role.

20 Q So were you turned down for tenure
21 or --

22 A I was not. I never -- I -- the
23 opportunity at HudsonAlpha predated the time that
24 I would have gone up for tenure. I had a number

1 of pre-reviews for tenure. There were no
2 concerns with that progress. But, based on both
3 funding as well as publication records, I wasn't
4 overly concerned with that.

5 But the opportunity to be able to do --
6 and the scale of operations at HudsonAlpha was --
7 was too good to turn down, as far as remaining at
8 Vanderbilt.

9 Q So you were neither granted tenure nor
10 denied tenure. Is that fair to say?

11 A That's fair to say.

12 I think the best evidence for the
13 relationship at Vanderbilt after my leaving was I
14 continued as an adjunct faculty in the same
15 department, again with change in title, for a
16 number of years after joining HudsonAlpha. So it
17 was a -- certainly, I wouldn't characterize it as
18 a negative departure from the institution. And I
19 still remain a collaborator with a number of
20 colleagues there.

21 Q Do you have a copy of your report in
22 front of you?

23 A I do.

24 Q Okay. What I'm gonna do is I'm gonna

1 try to go through, probably in -- in order,
2 portions of your report that I want to ask about
3 and try to make sure I don't cover things that
4 Miss Brown's already covered.

5 Can you look at page 5 of your report?

6 A Yes.

7 Q So there -- and I'm looking at number 2
8 on page 5, Acquired Somatic Gene Mutation.

9 Do you see that?

10 A I do.

11 Q And you say there that --

12 I'm skipping the sentences. If you
13 need to go back, feel free.

14 -- "Biological and lifestyle exposures,
15 such as viruses, obesity, hormones and chronic
16 inflammation, are also known to result in
17 cancer-causing mutations."

18 Right?

19 A I see that sentence.

20 Q Okay. Wouldn't you agree that the
21 association between obesity and cancer risk is
22 just that, an association and not a known
23 cause-and-effect relationship?

24 MS. O'DELL:

1 Object to the form.

2 A I would state that it is known that
3 cancer rates increase in a number of unhealthy
4 conditions, including obesity. But I am not
5 aware of a -- of any studies that have
6 illustrated a causal effect directly between
7 obesity and cancer.

8 MR. FERGUSON:

9 Q And, specifically, isn't it true that
10 there is no direct in vivo experimental evidence
11 that obesity causes cancer-causing mutations?

12 A I would have to review the literature
13 to -- before answering that question. But the
14 relationship between obesity and cancer risk
15 is -- is quite well established. And I think for
16 us to discuss that in more detail, we'd have to
17 start delving into some of the specifics around
18 the physiological changes related to obesity and
19 whether those specific physiological changes play
20 a role in cancer.

21 Q And, just below that, the last sentence
22 in that paragraph, you say, "These mechanisms may
23 be direct, such as radiation directly damaging
24 DNA, as well as indirect, such as an external

1 agent causing a cellular -- cellular reaction or
2 inflammatory response that then leads to DNA
3 damage or mutation."

4 What cellular reactions are you
5 referring to that result in DNA damage or
6 mutation?

7 A So the presence of reactive -- so a few
8 different things. Primarily, along the
9 discussions for today, the presence of reactive
10 oxygen species which can directly -- which are a
11 cellular reaction that can then cause -- directly
12 cause DNA damage.

13 There's protein oxidation effects that
14 are similar to that, in the sense that you have a
15 chemical change and a cellular component that
16 results in a -- in a protein activity change,
17 again leading to potential DNA damage.

18 And then you can have --

19 So those are two -- two examples of
20 cellular reactions to that.

21 Q And -- and maybe you just explained it,
22 but I wanted to make sure I'm clear. What is the
23 mechanism by which an inflammatory response
24 results in DNA damage?

1 A It varies. So the -- the --
2 "inflammatory response" is a bit general. So
3 depending on specific type of cellular
4 recruitment and cellular damage through the
5 release of cytokines, the release of oxidative
6 damaging materials from cells like granulocytes,
7 you know, or the -- even the cell's own
8 production of reaction to -- reactive oxygen
9 species, such as from the mitochondria, which is
10 the most common sync -- or most common source of
11 reactive oxygen species in the cell.

12 And, so, those are some examples of --
13 of that relationship between an inflammatory
14 response and that cellular reaction.

15 Q Reactive oxygen species are not the
16 same thing as inflammation; correct?

17 A I would say reactive oxygen species are
18 a hallmark of inflammation.

19 Q But they're not the same thing.

20 MS. O'DELL:

21 Object to the form.

22 A The -- well, they are --

23 Again, reactive oxygen species are a
24 component of inflammation. So they're -- the

1 words are two -- two different definitions, but
2 they are a component.

3 MR. FERGUSON:

4 Q Would you agree that reactive oxygen
5 species are a normal part of cell physiology?

6 A Yes, absolutely.

7 Q And the major source of reactive oxygen
8 species comes from inside the cell and is
9 produced in mitochondria?

10 A A source, and depending on the site of
11 the physiology. So a normal, healthy cell not
12 under stress or injury would be -- then, yes,
13 that's a true statement.

14 Under different physiological
15 conditions, that statement may not be true.

16 Q Can you distinguish reactive oxygen
17 species produced inside a cell from reactive
18 oxygen species produced outside the cell?

19 A What do you mean? So by -- by
20 "distinguish," you mean --

21 Q Can you tell the difference?

22 A I'm just thinking if there's a way to
23 measure.

24 So you can measure the effects of

1 exogenously introduced reactive oxygen species
2 and then compare that to the measurement of
3 endogenously produced reactive oxygen species.

4 But as far as determining the
5 difference if the cellular integrity is not
6 intact, I'm not aware of a method to do that.

7 Q Would you agree that generation of
8 reactive oxygen species is an inevitable
9 consequence of aging in aerobic organisms?

10 MS. O'DELL:

11 Object to the form.

12 A So reactive oxygen species are a --
13 are present at all stages of life. And aging, as
14 a biological phenomenon, is probably one of the
15 most variable phenomenon that exists.

16 And specific to reactive oxygen
17 species, the diet, lifestyle, and genetics of
18 that individual will drastically change that.

19 And a new area of research that my
20 laboratory has been undertaking for a short
21 time --

22 And, so, I don't have specific
23 publications, and it's really not -- I promise
24 it's not taking us too far afield.

1 -- but is the concept of your annual
2 age versus biological age. And my lab has some
3 assays that are based on epigenetics as well as
4 some metabolomic markers. And what we found --
5 now, in very, again, preliminary data -- that
6 individuals will vary by plus or minus 15 years
7 from physiological age to annual age based on,
8 again, a number of lifestyle factors not
9 important for this study.

10 But the point I'm making is the
11 discussion about level of reactive oxygen species
12 and its association with age is actually quite
13 variable based on the long -- or based on the
14 current physiological activity of that person.

15 Stated very simply, which is probably
16 something we all know, the better shape you're
17 in, the younger your physiology will appear. And
18 you can actually modulate that quite quickly,
19 meaning that a person who's 60 and has made poor
20 lifestyle choices can actually gain back quite a
21 bit of that physiological age quite quickly.

22 And so, again, to directly answer your
23 question, a annual age-related conclusion
24 regarding production of reactive oxygen species

1 would be very difficult.

2 MR. FERGUSON:

3 Q In your report, on this same page, you
4 discuss the fact that, even if someone has a
5 genetic mutation that predisposes them to cancer
6 doesn't mean that he or she is certain to get
7 cancer. Correct?

8 A That is correct.

9 Q So there is a -- a random component to
10 the effects of known cancer-causing agents.
11 Right?

12 MS. O'DELL:

13 Objection to form.

14 A There is a complicated relationship
15 between genetics, environment, and expose -- or
16 environment, including exposure and lifestyle,
17 and the progression of cancer.

18 Perhaps the -- a summary analogy is the
19 more predisposing mutations that an individual
20 has, it's -- it's equivalent to their body is
21 rolling the dice more often to collect a mutation
22 sufficient to cause cancer than somebody who does
23 not have the same genetic background.

24 And there's -- there's many, many lines

1 of evidence. Probably the most prominent is
2 BRCA1 and 2 mutation and the role it plays in
3 increased risk of breast and ovarian cancer.

4 MR. FERGUSON:

5 Q Wouldn't you agree that even the
6 inherited susceptibility cannot entirely explain
7 this random component of some people getting
8 cancer when exposed and some people not?

9 MS. O'DELL:

10 Objection to form.

11 A DNA -- so that, it's very
12 gene-dependent. So BRCA1 and 2 is the example
13 given. That is correct, that if you have a BRCA1
14 and -- 1 or 2 mutation, you are not guaranteed to
15 get cancer.

16 Corollary to that is if you do not have
17 a BRCA1 and 2 mutation, your relative risk for
18 cancer does not change, meaning that you're at no
19 less of a risk than somebody -- somebody else who
20 doesn't have that mutation.

21 I should state that there are other
22 genes. P53 is a good example that was mentioned
23 earlier. If you carry a mutation in that gene,
24 the probability that you'll get cancer, assuming

1 you don't die from something else, is almost
2 certain, meaning that it's in the mid to high 90
3 percents if you -- if you live until a late age.

4 MR. FERGUSON:

5 Q Further down this paragraph, you
6 indicate that "An inherited gene mutation could
7 instead make one more likely to develop cancer
8 when exposed to certain cancer-causing
9 substances."

10 Correct? That's your statement?

11 A Yes.

12 Q Can you provide any examples in which a
13 woman with an inherited mutation in a particular
14 gene has been demonstrated to have more
15 sensitivity to developing ovarian cancer as a
16 result of exposure to an environmental agent?

17 A Not for ovarian cancer specifically. I
18 would need to review --

19 There is a -- I've seen report of a
20 single gene related to ovarian cancer, which,
21 again, I would have to do a bit of searching to
22 be sure I'm naming the correct gene, but I --
23 where that has a much high- -- increased risk
24 specific to ovarian cancer, but I do not recall

1 if there was a measurement of any exogenous
2 exposure risk that amplified that effect or not.

3 But I think the -- as a general
4 premise, it is a -- well established in cancer
5 biology that any mu- -- any mutation that results
6 in a burden related to DNA repair, related to
7 cell cycle control, you are more susceptible to
8 cancer.

9 In one of our lines of research where
10 we do have some publications, in pediatric
11 cancer, I would simply point to in approximately
12 50 percent of adults who are survivors of
13 childhood cancer will develop a second cancer
14 event primarily because their -- the fact that
15 they developed a childhood cancer generally means
16 you are predisposed to that condition.

17 And -- and, as evidenced in the
18 observations we've done in the analysis of
19 thousands of patients in collaboration with
20 St. Jude and the children's oncology group, we've
21 identified now a ability to do genetic counseling
22 in those individuals and predict with very high
23 accuracy what their secondary cancer is likely to
24 be.

1 And the point of my mentioning this is
2 to illustrate that an early predisposition to --
3 or a significant predisposition to cancer that
4 results in a early cancer event, those
5 individuals show a lifetime increase in risk of
6 approximately -- they're -- they're approximately
7 six times, depending on the disease, to 13 times
8 more likely to get that -- to get a secondary
9 disease.

10 So there clearly is a relationship to
11 predisposition in -- in oncology -- or in rate of
12 cancer event.

13 Q Okay. And I appreciate your response.
14 But remember that my question was related to
15 ovarian cancer, and -- and we went a little
16 afield from ovarian cancer.

17 And I want to ask you another question
18 in that regard. Can you provide any example in
19 which a woman with an inherited mutation in a
20 particular gene has been demonstrated to have
21 more sensitivity to developing ovarian cancer as
22 a result of exposure to talcum powder?

23 MS. O'DELL:

24 Object to the form.

1 Answer the question.

2 A So the mechanism we proposed would be
3 independent of -- of that predisposition. But I
4 would have the opinion that an individual with
5 any predisposition mutation, regardless of the
6 gene but -- and -- in ovarian cancer, that they
7 would be a more fragile individual as -- when it
8 comes to this exposure under the mechanism that
9 we've been discussing today.

10 MR. FERGUSON:

11 Q Okay. And what I'm looking for is some
12 example or some literature in that regard.

13 A I would -- I would have to -- I would
14 have to look --

15 Q Okay.

16 A -- to see.

17 Q So what you've told me is that's your
18 opinion, but you don't have any references for it
19 as you sit here?

20 MS. O'DELL:

21 Objection to form.

22 A So my -- what was -- I was requested to
23 provide this biologically plausible mechanism,
24 and part of that request was not necessarily

1 include the influence on that mechanism that
2 specific gene mutations or inherited risks may
3 have within relation to ovarian cancer.

4 So I'd certainly be delighted to pause
5 for a moment and take -- you know, and -- and
6 work on that -- give you that -- see if I can
7 give you that specific example.

8 MR. FERGUSON:

9 Q But you can't as you sit here?

10 A I cannot.

11 Q Okay. So let's look at -- further down
12 on page 5, you have a section entitled "The Role
13 of Genetics in Ovarian Cancer." Correct?

14 A Correct.

15 Q And I want to look at a reference that
16 you -- you have cited. And let me mark this as
17 an exhibit, please. I guess I can mark it.

18 (DEPOSITION EXHIBIT NUMBER 21
19 WAS MARKED FOR IDENTIFICATION.)

20 MR. FERGUSON:

21 Q Exhibit 21 is the Nunes article. Have
22 you seen that?

23 A I have, yes.

24 Q Okay. So if we look at page 5, at top

1 of the page, you indicate that ovarian cancer is
2 the major cause of death from gynecologic disease
3 and the second most common gynecologic malignancy
4 worldwide; correct?

5 A Correct.

6 Q And then in your report you cite Nunes
7 and Serpa, the article we've just marked as
8 Exhibit 21, as well as Siegel and Torre; correct?

9 A Yes.

10 Q If we look at page 2 of the Nunes
11 article, the exact same sentence appears on -- at
12 the bottom of page 2 under the heading of
13 "Ovarian Cancer, an Overview"; correct?

14 A Correct.

15 Q Right.

16 A That's correct.

17 Q Okay. And it's --

18 A It's not quite the same sentence, given
19 that it's the same initial statement, not an
20 identical sentence.

21 Q Very close to identical?

22 A Well, they -- they both -- they both
23 introduce the same facts.

24 Q Okay. Then if we go down a little bit

1 further and you have a sentence that starts
2 "epithelial ovarian cancer." Correct?

3 MS. O'DELL:

4 On page 6 there?

5 MR. FERGUSON:

6 Yeah. I apologize. Yeah, it is.

7 A Yep.

8 MR. FERGUSON:

9 Q It's on page 6. It's the, I believe,
10 the last sentence of the partial paragraph at the
11 top of 6. See it?

12 A I do.

13 Q Okay. And you say, "Epithelial ovarian
14 cancer (EOC) includes most malignant ovarian
15 neoplasms" -- you cite Chan, 2006 -- "that can be
16 classified based on morphologic and molecular
17 genetic features into the following types:
18 Serous" -- and, in parentheses, "(OSC) low and
19 high grade); endometrioid (EC), clear cell,
20 (OCCC), and mucinous (MC) carcinomas."

21 Correct?

22 A Correct.

23 Q Okay. And then if we look back at page
24 2 of Nunes, in the second sentence of the first

1 paragraph under "Ovarian Cancer, an Overview,"
2 the nearly identical sentence appears there.

3 Correct?

4 MS. O'DELL:

5 Object to the form.

6 A The two sentences stating the same
7 fundamental facts regarding ovarian cancer and
8 the histological types are -- yes, I agree.

9 MR. FERGUSON:

10 Q With almost the same wording.

11 MS. O'DELL:

12 Object to the form.

13 A They have similar wording.

14 MR. FERGUSON:

15 Q Remarkably similar; correct?

16 MS. O'DELL:

17 Object to the form.

18 A I wouldn't call it -- so they --

19 Again, we're stating fundamental basic
20 facts around histological type and following a
21 number of, again, factual observations for what
22 the state of the art for genetic knowledge
23 in -- in different genes and different proteins
24 is as it relates to our understanding of -- of

1 cancer with, again, appropriate reference for
2 those -- for those studies.

3 MR. FERGUSON:

4 Q And then if we look at the following
5 paragraphs, the first full paragraph there on
6 page 6, in your report you have a sentence that
7 starts "low grade OSC cases generally have
8 genetic alterations" in a number of items you've
9 listed; correct?

10 A Correct.

11 Q Okay. And that sentence ends with the
12 words or "p13/Ras/Notch/FOXm1." Correct?

13 A Correct.

14 Q Okay. And then if we go back to Nunes,
15 if you look at that same paragraph we've been
16 talking about -- and those -- there's an
17 introductory phrase that you don't have, and then
18 it starts with "low grade OSC generally
19 comprising." Slightly different wording, but you
20 list the same types of receptors and the same
21 types of items. Correct?

22 A Yes. That's providing a review of,
23 again, the known associations between specific
24 ovarian subtypes and their most commonly referred

1 genetic information or genetic predis- --

2 sorry -- mutated genes. So I'm -- that's right.

3 Q Okay.

4 A They are -- they are similar in that
5 both are, again, introducing factual information
6 about the current knowledge in ovarian cancer in
7 this literature, again pointing out that
8 referencing the papers that they both came from,
9 being the Nunes as well as the appropriate
10 references.

11 Q Okay. And, then, the paragraph below
12 that starts endo- -- "endometrioid carcinoma,"
13 paren, "(EC)." Correct?

14 A Correct.

15 Q If we look --

16 And then that goes all the way to the
17 word "mucin-coding genes" with two citations;
18 correct?

19 A Correct.

20 Q If we look at 2 and the top of page 3
21 in Nunes, there's a sentence that starts "EC."
22 It does not spell out endometrioid carcinoma. Do
23 you see that four lines from the top? I'm sorry.
24 Four lines from the bottom --

1 MS. O'DELL:

2 I'm sorry.

3 MR. FERGUSON:

4 Q -- on page 2.

5 A Yes.

6 MR. FERGUSON:

7 Sorry. Leigh, it's on page -- the
8 bottom of page 2.

9 MS. O'DELL:

10 Oh, I'm there. When you said the top,
11 I got --

12 MR. FERGUSON:

13 No worries. That's -- my mistake.

14 Q Okay. It says "EC subtypes," and then
15 it goes to mucin-coding genes on the top of page
16 3. Correct?

17 A Correct.

18 Q Again, that paragraph is nearly
19 identical to the one in your report. Correct?

20 MS. O'DELL:

21 Object to the form.

22 MR. FERGUSON:

23 Q Same word, same order, same citations;
24 correct?

1 MS. O'DELL:

2 Object to the form.

3 A So my -- my report is similar to the
4 review article. It -- it's listing the subtypes
5 of ovarian cancer and -- based on the Nunes
6 paper, which is a 2018 publication, so a more
7 current review. I'm, again, providing that
8 referenced information about the -- the -- this
9 observation.

10 Q You're citing the same references as
11 Nunes; correct?

12 A Yes.

13 Q You cite the -- the various gene --
14 expression of gene in the same order they do,
15 so --

16 Correct?

17 A Yes.

18 Q And is that just coincidental? That's
19 just happened? You happened to have put this
20 paragraph in the same order with the same
21 notations as -- as Nunes?

22 MS. O'DELL:

23 Object to the form.

24 A Well, I'm listing the same information

1 that's contained in the Nunes paper. And seeing
2 as that -- this was a review of the literature
3 with -- you know, based on the state of the art,
4 the Nunes review is exactly that. And, again,
5 I'm -- I'm repeating the information regarding
6 the specific gene information as it relates to
7 this -- this ovarian cancer risk and -- and --
8 and, again, appropriately citing the basic
9 studies as Nunes did.

10 MR. FERGUSON:

11 Q With virtually the same wording?

12 A With similar wording, yes.

13 Q Let's look at page -- page 7.

14 MS. O'DELL:

15 His report?

16 MR. FERGUSON:

17 Q Yeah. I apologize. Your report.

18 We can set Nunes aside now.

19 You have a paragraph starts -- that
20 starts "individuals can inherit mutations in
21 BRCA1, BRCA2 or p53."

22 See it?

23 A Uh-huh.

24 Q And you say, "These defects allow

1 additional mutations to accumulate in cells and
2 lead to a higher probability of cells being
3 cancerous."

4 Correct?

5 A Correct.

6 Q And you've indicated earlier in your
7 report that cancer is caused by mutations.

8 Correct?

9 A Correct.

10 Q And you say here that mutations in
11 BRCA1, BRCA2 or p53 can result in the
12 accumulation of additional mutations in cells.

13 Correct?

14 MS. O'DELL:

15 Object to the form.

16 A Yeah. I made the statement that BRCA1,
17 BRCA2 and p53, they can be inherited and then, in
18 turn, positive for those gene mutations.

19 MR. FERGUSON:

20 Q Okay. Would you --

21 A So I guess if you could ask the
22 question again to make sure I understand it.

23 Q Well, let me -- doesn't this paragraph
24 mean, in your comments here, that BRCA1, BRCA2,

1 or p53 mutations can be considered causes of
2 cancer?

3 MS. O'DELL:

4 Object to the form.

5 A No. Not -- not specifically causal. I
6 think the -- each of these -- as we've discussed,
7 each of these genes, BRCA1 and BRCA2, or starting
8 with BRCA1 and BRCA2, increase the probability of
9 a -- of a person -- generally women -- getting
10 breast or ovarian cancer but do not exclusively
11 mean somebody with that mutation will get cancer.

12 So, with that knowledge, I would not
13 consider BRCA1 and BRCA2 mutation alone
14 sufficient to cause cancer. It increased the
15 risk.

16 And, as we talked about, p53 is a bit
17 more of a higher-risk gene, and the question as
18 to whether or not it is possible for someone to
19 have a -- what the rate of someone having a p53
20 mutation and not getting cancer, I believe, is
21 currently unknown. But there, again, is a much
22 higher probability of developing -- developing
23 cancer.

24 MR. FERGUSON:

1 Q And then the last line there of page 7,
2 you say, "The lifetime risk for ovarian cancer is
3 approximately 40 percent for BRCA1 carriers and
4 15 to 20 percent for BRCA2 carriers."

5 Correct?

6 A Correct. Based on -- based on the
7 study that I referenced, yes.

8 Q Right.

9 And -- and the -- the -- if we look at
10 the increased risk of 40 percent as compared to
11 the risk of cancer in the -- of ovarian cancer in
12 the general population, that's a 25-fold increase
13 for BRCA1 and about a 7- or 8-fold increase for
14 BRCA2; correct?

15 MS. O'DELL:

16 Object to the form.

17 A I -- I would have to -- to determine
18 that. But I would say so. I'm certainly
19 comfortable stating that the lifetime risk for
20 ovarian cancer is approximately 40 percent. I'd
21 have to verify your -- your math about that
22 indicating a 25-fold increase.

23 MR. FERGUSON:

24 Q Do you know what the rate in the

1 general population of ovarian cancer is?

2 A It's fairly low. If I -- thinking of
3 the cohort studies that were reviewed as part of
4 this, it was roughly a hundred to 200 cases per
5 30- to 40,000 women in those -- in those studies,
6 so relatively low.

7 Q And if we go to the top of the next
8 page, you say -- it's page 8 -- "Therefore, the
9 presence of mutations in the BRCA genes do not
10 guarantee that carriers will get cancer. The
11 presence of these mutations increases a person's
12 risk of developing cancer when exposed to a
13 carcinogen."

14 Correct?

15 A Correct.

16 Q And you cite Park, Vitonis, and Wu for
17 that. Is that correct?

18 A That's correct.

19 Q Looking at Park, isn't it true that
20 Park does not supply any evidence to support your
21 claim that mutations in BRCA1, BRCA2 and/or p53
22 increase a person's risk of developing cancer
23 when exposed to a carcinogen?

24 A I'd have to remind myself of what's in

1 Park.

2 Q Are you going through the entirety of
3 the article?

4 A I'm just reminding myself the content
5 to see if I could find something that was
6 specifically related to your question about the
7 presence of a BRCA1 or 2 mutation.

8 Q Okay. Is the BRCA1, BRCA2, p53, any of
9 those even mentioned in the article?

10 And -- and I'm not sure we'll have time
11 for you to go through each one of them in this
12 much --

13 You've got -- you cited them for these
14 propositions. I'm trying to ask you why you
15 cited them for this proposition.

16 A I -- I'd have to look in more detail.
17 I don't have a specific answer regarding the --
18 regarding BRCA1 --

19 Q Okay.

20 A -- I'm sorry -- BRCA genes.

21 I would suspect the Park reference was
22 more in the discussion of overall relative risk
23 of developing cancer and not necessarily
24 exclusive to the presence of a mutation.

1 So the -- the Park paper does discuss
2 the relationship of ovarian cancer risk relative
3 to benign gynecological conditions.

4 Q And -- and your comment that you've
5 cited these studies for is the presence of these
6 mutations increases a person's risk of developing
7 cancer when exposed to a carcinogen. And these
8 mutations would be what you've been talking about
9 in this paragraph, the B -- the BRCA1, BRCA2, and
10 p53; correct?

11 MS. O'DELL:

12 Object to the form.

13 A The sentence is worded, "The presence
14 of these mutations increases a person's risk of
15 developing cancer when exposed to a carcinogen."

16 MR. FERGUSON:

17 Q Right. Right.

18 And, for example, in Vitonis, isn't it
19 true that BRCA1, BRCA2 and p53 were not even
20 determined in that study and, instead, Jewish
21 ethnicity was used as a surrogate for a woman's
22 risk of having a mutation in one of these genes?

23 Do you recall that --

24 A Again, I would have --

1 Q -- one way or the other?

2 MS. O'DELL:

3 Objection.

4 A I would have to review the -- review
5 the paper. Because part of the review is to
6 be -- include appropriate references with regards
7 to ovarian cancer risk, and those may -- I think
8 those publications provide some information in
9 that space.

10 MR. FERGUSON:

11 Q All right. But when you cite studies
12 for a statement in your report, shouldn't the
13 studies relate to that statement?

14 MS. O'DELL:

15 Object to the form.

16 A Well, the studies relate to a person's
17 risk of developing cancer. But I -- I think
18 it -- it doesn't change the accuracy of the
19 presence of the mutation relative to that risk.
20 But the -- I don't have a -- a good answer as far
21 as relationship of BRCA1 and 2 to the Park paper.

22 MR. FERGUSON:

23 Q And -- and, then --

24 Well, we talked about Vitonis, too.

1 And then let's get to Wu.

2 MS. O'DELL:

3 Object to the form. You didn't comment
4 specifically about Vitonis, if you've got an
5 issue with Vitonis. You know, it's not fair to
6 assume that because I don't think you asked a
7 direct question.

8 MR. FERGUSON:

9 Okay. I thought I did, but I could be
10 mistaken.

11 MS. O'DELL:

12 You mentioned it, but I don't think
13 you -- I think it was more you rather than asking
14 a question.

15 MR. FERGUSON:

16 Q With regard to Wu, do you recall that,
17 in Wu, BRCA1, BRCA2, and p53 inherited carrier
18 mutation status were not even determined in that
19 study? Do you recall that --

20 A The --

21 Q -- one way or the other?

22 MS. O'DELL:

23 Object to the form.

24 A The Wu paper specifically discussed

1 nongenetic risk factors.

2 MR. FERGUSON:

3 Q Let's go to the next paragraph, and
4 there you talk about single nucleotide variance,
5 SNVs; correct?

6 A Towards the bottom of the paragraph.
7 As -- in terms of modifiers, yes.

8 Q Yeah. Are -- are single nucleotide
9 variants mutations?

10 A Yes.

11 Q Do most SNVs result in functionally
12 defective proteins?

13 A Statistically speaking on a genome-wide
14 basis, no.

15 So a -- a single nucleotide variant is
16 a variant at any point. And if we consider
17 statistically that about 1 percent of the genome
18 encodes proteins, again, it's statistically less
19 likely that any SNV would affect a protein.

20 Q Okay. Let's look at the next
21 paragraph. There you talk about Lynch syndrome;
22 correct?

23 A Correct.

24 Q And you make a statement that Lynch

1 syndrome patients have an increased risk of
2 cancer when exposed to a carcinogen. Correct?

3 A Correct.

4 Q What carcinogens are you referring to?

5 A I'm not -- not referring to a specific
6 carcinogen. I'm using the term "carcinogen" to
7 refer to an insult that would result in DNA
8 damage specifically because, similar to the BRCA
9 mutations, Lynch syndrome impairs DNA mismatch
10 repair.

11 So that defect alone is not sufficient
12 to result in a cellular transformation, so
13 something else has to occur. And when we
14 consider that carcinogens are -- the term
15 "carcinogen" generally refers to something that
16 has the potential to damage cellular components
17 or DNA, it's putting the --

18 Inability to repair along with the
19 presence of a carcinogen is where that sentence
20 comes from.

21 Q So -- and I want to make sure I
22 understand what you're saying. Are you saying
23 that Lynch syndrome patients have an increased
24 risk of developing cancer after exposure to a

1 carcinogen, just like everyone else?

2 A No. I'm stating that Lynch syndrome --

3 MS. O'DELL:

4 Object to the form. Excuse me.

5 A Lynch syndrome is a hereditary
6 condition that increases the overall risk of
7 cancer to an individual, similar to BRCA1 and 2
8 mutation.

9 MR. FERGUSON:

10 Q So you -- are you claiming that Lynch
11 syndrome patients have a greater increase in
12 relative risk when exposed to a particular
13 carcinogen than do people without Lynch syndrome?

14 MS. O'DELL:

15 Object to the form.

16 A No, I'm not making that statement, to a
17 specific carcinogen.

18 MR. FERGUSON:

19 Q In your next paragraph you talk of --
20 you start with "Myriad Genetics," and you say,
21 "As with all inherited traits, a positive family
22 history is the strongest indicator of the
23 presence of genetic risk alleles in an
24 individual."

1 Correct?

2 A Correct.

3 Q Isn't it true that many women who have
4 inherited mutations like BRCA1 or BRCA2 and genes
5 that predispose to ovarian cancer development do
6 not have a family history of breast or ovarian
7 cancer?

8 A So the -- your -- your question is a
9 little bit different than the statement. So
10 the -- if I could clarify the statement in the
11 report, it is more that a positive family history
12 would be a likely indicator that someone has a
13 genetic risk variant such as BRCA1 and 2.

14 Q Isn't it true that family history is
15 not a sensitive or specific indicator of
16 whether -- of whether a particular woman has
17 inherited a mutation in a gene associated with
18 increased risk of ovarian cancer?

19 MS. O'DELL:

20 Object to the form.

21 A I would say that family -- I would ask
22 to define "sensitive" or "specific," because in
23 genetics overall, family history remains a
24 valuable and important characteristic in terms of

1 determining the genetic component of -- of any
2 disease, cancer included. And, so, if there's
3 something exact regarding its sensitivity or
4 specificity that I can comment on, I will if I
5 know the answer. But...

6 MR. FERGUSON:

7 Q In -- in the top of the page -- of
8 page 9, the next page, you indicate, "Because of
9 the large number of individuals tested and the
10 ability to trace their genetic inheritance, the
11 genes involved in cancer development are well
12 established."

13 Is that correct?

14 A Correct. That's what I state. I did
15 make that statement.

16 Q And given that they're well
17 established, can you name all of the inherited
18 genes that have been identified as being
19 associated with an increased risk of ovarian
20 cancer?

21 A No, not -- I can't name them all off
22 the top of my head, no. There's something in the
23 neighborhood of 500 to -- 500 genes of strong
24 association of cancer risk and progression, some

1 number higher than that if you're looking at
2 indirect or genetic complex formation.

3 You know, depends how far down the
4 cellular control and signal transduction and
5 growth and proliferation road that we go as far
6 as how many genes. But I'm sure, as everyone
7 well appreciates, everything in biology is
8 interrelated in some form.

9 And, so, it -- but I would say this
10 statement here is that our ability to look at
11 large-scale genetic analysis in individuals of a
12 variety of cancer types, given the number of
13 individuals affected by cancer and the analysis
14 of their genetics, we've been able to identify
15 many of -- many of the fundamental or most --
16 perhaps most of the fundamental genes involved in
17 that initial disease initiation or progression.

18 It's important that it is not a
19 comprehensive list. Hence, it is not "all," but
20 there are a large number of genes that are well
21 established.

22 Q Okay. Let's look at the next page, 10.
23 And you have a paragraph that starts
24 "Macrophages."

1 A Uh-huh.

2 Q And the last sentence says, "Generally
3 speaking, macrophages can increase inflammation
4 or decrease inflammation, depending on the
5 cytokines released."

6 Correct?

7 A Correct.

8 Q So, with that statement, do you agree
9 that inflammation can have both protumorigenic
10 and antitumorigenic effects, depending on
11 context, just as you state here for macrophages?

12 MS. O'DELL:

13 Object to the form.

14 A No, I -- I would not agree with that.
15 I -- I don't know of any evidence of that, that
16 inflammation, as a physiological phenomenon, acts
17 as an antitumor effect.

18 MR. FERGUSON:

19 Q Going to the next page, the page 11 --
20 I'm trying to get through this
21 hopefully within the next 15 minutes.

22 -- under the role of inflammation in
23 ovarian cancer --

24 Are you with me there?

1 A I am.

2 Q And you're obviously talking about the
3 role of inflammation there. Isn't it true that
4 no published animal model has ever shown that
5 inducing inflammation induces the development of
6 ovarian cancer?

7 MS. O'DELL:

8 Object to the form.

9 A We've been -- earlier today we were
10 discussing some animal models as it relates to --

11 MR. FERGUSON:

12 Q Yeah. You and Miss Brown talked about
13 a number of animal models.

14 A Yeah.

15 Q And -- and what I'm trying to ask you,
16 is there any of those animal models or any others
17 that have ever shown that inducing inflammation
18 induces the development of ovarian cancer?

19 A I didn't -- I didn't look specifically
20 for an animal study of that type in the process
21 of developing the report.

22 Q Later down that page, you talk about
23 two models. "The literature reviews as well as
24 many direct studies feature the immune system as

1 being an important mediator of ovarian
2 carcinogenesis via two models, chronic
3 inflammation and incessant ovulation."

4 Correct?

5 A Correct.

6 Q Is it your opinion that incessant
7 ovulation is a form of chronic inflammation?

8 A It is not.

9 Q Isn't it true that there's no
10 pathological evidence in humans that perineal
11 talc users have ovarian inflammation?

12 MS. O'DELL:

13 Object to the form.

14 A I'm thinking.

15 I would have to review the --

16 I'm sorry. That's -- it's --

17 MR. FERGUSON:

18 Q Okay.

19 A I would -- again, I would have to look
20 more carefully for that. I can't -- I can't name
21 a study of that type right now.

22 Q So I think you've said previously --

23 Are you done looking?

24 I understood you couldn't give me

1 anything on that, so that's -- that's fine.

2 Let's move on.

3 A Okay.

4 Q I think you've stated earlier that your
5 opinion in this case is based on the totality of
6 what is included in the product, the talcum
7 powder products. Is that correct?

8 A Correct.

9 Q So you're -- you cannot distinguish
10 the -- the carcinogenicity of the constituent
11 parts of the talcum powder products, correct,
12 including the fragrance?

13 MS. O'DELL:

14 Object to the form.

15 A I -- I was -- I was not asked to -- to
16 provide that delineation. And, so, instead,
17 subsequent to seeing some of the other expert
18 reports, we began with talcum powder as a product
19 and then have since learned more about the
20 constituent components, including asbestos,
21 fragrance, potential for heavy metals, which I
22 understand or I've observed that there's a
23 variety of testing documents that -- that show a
24 variety of results.

1 So, to answer your question, I did not
2 specifically evaluate the individual specific
3 components in any -- in any individual product as
4 it relates. Instead, remained focused on the
5 mechanism for the complete -- complete product.

6 MR. FERGUSON:

7 Q And you've made reference to heavy
8 metals throughout your testimony on occasion. Do
9 you recall that?

10 A I do.

11 Q Do you have any opinions that any of
12 these heavy metals contribute to the inflammation
13 process that you've been talking about?

14 A The -- to the inflammation --

15 I'm not aware of any direct evidence
16 for heavy metal contribution to the inflammation
17 process that we've been discussing. Instead, the
18 heavy metals, particularly chromium, caught my
19 attention because of its well-established ability
20 to directly damage DNA and, therefore, you know,
21 potentially play a role in carcinogenesis.

22 Q Do you have any knowledge or opinion
23 about how much chromium you claim is in the -- in
24 the body powder products?

1 MS. O'DELL:

2 Object to the form.

3 A I wasn't asked to evaluate the amount
4 of chromium or whether it was sufficient for
5 damage. It was more reviewing. I would have to
6 defer to other experts who have done the testing
7 on the products.

8 MR. FERGUSON:

9 Q So you have no opinion on that?

10 MS. O'DELL:

11 Object to the form.

12 A I'm sorry. An opinion on the amount of
13 chromium?

14 MR. FERGUSON:

15 Q Correct.

16 A Again, I wasn't asked to generate such
17 an opinion.

18 Q I think -- I think I'm almost done.

19 Isn't it true that published data have
20 demonstrated that talc is not genotoxic and does
21 not cause mutations?

22 MS. O'DELL:

23 Object to the form.

24 A I'm not aware of a study that

1 specifically looked at the genotoxicity of -- of
2 talc. And I think it would certainly warrant
3 defining which type of talc and components
4 therein. But I'm -- I'm not aware of a study
5 that has concluded that there are no genotoxic
6 effects of any type of talc.

7 MR. FERGUSON:

8 Q Would you agree there's no evidence
9 that talc causes sister chromatid exchange or
10 unscheduled DNA synthesis?

11 MS. O'DELL:

12 Object to the form.

13 A I didn't -- I didn't review the
14 literature for those two specific phenomenon. I
15 would have to, again, specifically look or review
16 for that.

17 MR. FERGUSON:

18 Q So, as you sit here, you have no
19 opinion as to whether talc is or is not
20 mutagenic?

21 MS. O'DELL:

22 Object to the form.

23 A No. We've -- so talc in general,
24 particularly in its -- in its form of fibrous

1 talc with asbestiform bodies, I think would be
2 very reasonable to state that it has mutagenic
3 properties.

4 MR. FERGUSON:

5 Q And can you cite me any literature for
6 that?

7 A I would simply refer to the -- much of
8 the body of asbestos literature for the -- for
9 that.

10 MR. FERGUSON:

11 I think that's all I have. I'll turn
12 it over to someone else to ask some questions.

13 MS. BROWN:

14 Anybody with some more?

15 MS. O'DELL:

16 I'm going to take a break for a few
17 minutes.

18 VIDEOGRAPHER:

19 Going off the record. The time is
20 4:54 p.m.

21 (OFF THE RECORD.)

22 VIDEOGRAPHER:

23 We're back on the record. The time is
24 5:20 p.m.

1 EXAMINATION

2 BY MS. O'DELL:

3 Q Dr. Levy, I have just a few follow-up
4 questions for you.

5 I'm gonna ask you to turn to page 14 of
6 your report.

7 And earlier today --

8 I'm going to ask, Doctor, if you could
9 put the exhibits in front of you, and we'll pull
10 those out.

11 But earlier today you were asked about
12 a letter from the FDA that was marked as Exhibit
13 Number 16, and if you could pull that out of your
14 stack there. And, specifically, if you'll turn
15 to page 4 of the letter.

16 And you'll recall that this letter was
17 written in 2014. Do you remember that?

18 A Yes.

19 Q And if you look, however, at page 4 of
20 the letter, it appears that the FDA's review of
21 the relevant toxicity literature stopped at the
22 year 2008. Fair?

23 MS. BROWN:

24 Objection to the form.

1 MS. O'DELL:

2 Q Did the FDA's review of the toxicity
3 literature stop in 2008?

4 A Yes.

5 Q And if you look at page 14 of -- of
6 your report, your review of the literature
7 included multiple references that were published
8 after 2008?

9 MS. BROWN:

10 Form.

11 A That's correct.

12 MS. O'DELL:

13 Q And, in fact, you cited Shukla that was
14 published in --

15 Was Shukla published in 2009?

16 A Yes. The reference is in the report to
17 2009.

18 Q Yes.

19 And, in addition to that, did you cite
20 other references in support of your opinion that
21 talc powder causes inflammation that were dated
22 and published after 2008?

23 A I did.

24 Q And, so, the suggestion by counsel for

1 Johnson & Johnson that somehow the FDA had
2 reviewed the literature for toxicity up until the
3 date of this letter would have been incorrect?

4 MS. BROWN:

5 Objection to the form of the question.

6 A As -- as we discussed, the -- the
7 letter from the FDA dated April 1st, 2014, states
8 to include literature from 1980 to 2008.

9 MS. O'DELL:

10 Q Let me ask you --

11 You can put that aside, Dr. Levy.

12 Thank you.

13 And I want to ask you to pull out of
14 the stack the Exhibit 17, which is the Buz'Zard
15 paper.

16 A I have it.

17 Q And if you'll turn to page 581.

18 A Okay.

19 Q And just to orient our discussion,
20 counsel for Johnson & Johnson suggested that --
21 that this paper showed a decrease in reaction or
22 reactive oxygen species at the longest time
23 interval. Do you recall that discussion?

24 MS. BROWN:

1 Objection to the form of the question.

2 A Yes, we -- we had a discussion
3 regarding the results shown in Figure 3, the
4 level of exposure of talc as well as its
5 duration. Sorry. The talc dose as well as
6 duration.

7 MS. O'DELL:

8 Q And in the -- if you'll look at
9 Figure 1, Doctor, explain to us, please, what
10 Figure 1 describes in terms of the viability of
11 the cells at the 72-hour mark.

12 A So the -- so Figure 1 is a graph
13 describing percent cell viability versus the
14 different normal or variant cells at a 24-hour
15 and 72-hour time point, two different ovarian
16 cancer cell lines, as well as doses of talc from
17 zero micrograms per milliliter up to 500
18 micrograms per milliliter, and each of those is
19 applied.

20 And at the 72-hour time point in both
21 cell lines, OSE2a and GCA1 -- GC1a shows a
22 decrease in cellular viability that is
23 dose-dependent in each of the four cell lines.

24 Q Okay. And --

1 A Sorry. Each of the two cell lines.

2 Q And is it fair to say that the reason
3 you don't see dose response, you know, at the --
4 at the greatest magnitude is because the cells
5 essentially die?

6 MS. BROWN:

7 Objection to the form.

8 A Well, I would say if we consider the
9 results displayed in Figure 1 in relation to the
10 results displayed in Figure 3, an ex- -- an
11 explanation for the concentrating on the 500 --
12 the highest dose, the 500 micrograms per
13 milliliter, in the talc exposure, the decrease in
14 cellular viability is an -- is an explanation --
15 could be an explanation for the decrease in
16 reactive oxygen species.

17 MS. O'DELL:

18 Q Okay. Thank you, Doctor.

19 And if you'll put that aside and turn
20 to Exhibit 7, which was the Hamilton paper we
21 spent quite a lot of time on earlier.

22 Do you recall the -- that discussion
23 regarding the Hamilton paper?

24 A I do.

1 Q And what was the purpose for which you
2 cited the Hamilton paper?

3 A That it was one of the available animal
4 studies looking at the effects of talc on a rat
5 ovary.

6 Q And did the paper show that there was a
7 increase in inflammation as result of talc?

8 A Yes, in the form of foreign body
9 granulomas observed in five of the injected
10 ovaries.

11 Q And you're looking at, I guess, that
12 last sentence on page 103 and carrying over to
13 the -- to the narrative on page 105?

14 A Cellular foreign body?

15 Q Yes.

16 A Foreign body granulomas without any
17 surrounding inflammation were seen in five of the
18 injected ovaries. And similar lesions were not
19 uncommonly noted in the supracapsular fat in the
20 connective tissue matrix of the capsule.

21 Q And if you'll look down in the
22 discussion section, Dr. Levy, the first paragraph
23 there in your -- where -- beginning
24 "Unfortunately," does it appear that talc also

1 induced fibrosis --

2 MS. BROWN:

3 Objection to form.

4 MS. O'DELL:

5 Q -- in the rats?

6 A The manuscript makes the statement
7 that, "Unfortunately, bursal distention occurred
8 as an unforeseen complication" and further states
9 that this probably resulted from talc-induced
10 fibrosis and obliteration of the small channel
11 which normally allows communication between the
12 cavity where the ovary lies and the perineum.

13 Q And though the authors concluded that
14 neoplastic changes were not seen, the authors did
15 find evidence of inflammation in their study?

16 A That's correct.

17 Q Prior to becoming involved in the
18 litigation, Dr. Levy, did you hold the opinion
19 that inflammation is a cause of cancer?

20 A As -- as we've discussed earlier, I
21 certainly held the opinion that, you know,
22 inflammation is a significant and necessary
23 component of cancer progression.

24 Q And has that been -- that general

1 principle been published in the peer-reviewed
2 literature?

3 A It has.

4 Q And, in regard to ovarian cancer, prior
5 to becoming involved in the litigation, did you
6 hold the opinion that inflammation was a part of
7 the development of ovarian cancer?

8 A Yes.

9 Q And has that been researched and that
10 research published in the peer-reviewed
11 literature?

12 A It has.

13 Q In the same way, has the fact that
14 talc, talcum powder, induces inflammation been
15 published in the peer-reviewed literature?

16 MS. BROWN:

17 Objection to the form.

18 A Yes.

19 MS. O'DELL:

20 Q And you were asked whether there was
21 evidence that talc caused inflammation in humans.
22 Do you recall that question?

23 A I do.

24 Q And based on your exhaustive review of

1 the literature, what evidence would you point to
2 undergirding your opinion that talc causes
3 inflammation in humans?

4 A I think considering the molecular
5 mechanism we were discussing of the recent paper
6 by Saed, et al., again, that we discussed earlier
7 today is a fairly in-depth set of experiments to
8 examine the specific inflammatory response
9 of -- of human cells to -- to talcum powder.

10 Q In addition to the Saed publications,
11 would you -- would you include the Shukla 2009
12 paper in your consideration of talc causing
13 inflammation in humans?

14 A Yes.

15 MS. BROWN:

16 Form.

17 MS. O'DELL:

18 Q You were asked about your methodology
19 numerous times today, and can -- would you
20 describe in -- in general the methodology you
21 have used in reaching your opinions in this case?

22 A Yes. To clarify or perhaps expand on
23 the earlier discussions, my methodology involved
24 a literature review to examine the totality of

1 the information available to the role that talcum
2 powder plays in inflammation in ovarian cancer.

3 And, so, that methodology involved,
4 first, a review of the literature and then a
5 development of a report and then a synthesis of a
6 biologically plausible mechanism where the basis
7 of that plausibility was to ask if each of the
8 different component steps that are described in
9 that mechanism was supported by peer-reviewed
10 research. First, does talc cause inflammation?
11 Second, does inflammation cause cancer? And
12 then, third -- or does inflammation cause ovarian
13 cancer? And then, third, is there -- is that
14 supportive of a overall mechanism of cancer
15 progression and metastasis?

16 Q Can that methodology be replicated?

17 A Certainly. I think, you know, anyone
18 with a similar -- similar background and
19 experience who -- who undertook the same
20 activities would likely -- certainly likely come
21 up with the same -- same conclusions.

22 Q Did you rely on the IARC monograph in
23 relation to nickel, chromium, and cobalt in
24 reaching your opinions in this case?

1 MS. BROWN:

2 Objection to the form.

3 A I -- so the -- the number of IARC
4 publications were certainly in the material that
5 was reviewed for -- for my -- for my report.

6 MS. O'DELL:

7 Q Based on your review of the literature,
8 is it your opinion that nickel causes
9 inflammation?

10 A Yes. The IARC -- the -- the
11 characterization of those compounds, nickel as
12 well as chromium, among others, are -- would have
13 an inflammatory response.

14 Q You were asked questions earlier
15 today -- actually, not so much earlier -- a few
16 minutes ago regarding the Park paper. And you
17 cited the Park paper on page -- I think it was 8
18 of your report.

19 A Yes.

20 Q And let me show you what I'm marking as
21 Exhibit 22 to your deposition.

22 (DEPOSITION EXHIBIT NUMBER 22
23 WAS MARKED FOR IDENTIFICATION.)

24 MS. O'DELL:

1 Q Is this the Park paper that you
2 referenced --

3 MS. BROWN:

4 Counsel, do you have a copy for us?

5 MS. O'DELL:

6 I don't. I'm assuming -- I don't think
7 Ken marked it, but I'm assuming he has a copy.

8 Q Is that the Park paper that you
9 referenced in your report, Dr. Levy?

10 A It is.

11 Q And if you'll turn to page 8 of the
12 paper, about midway down the first column, maybe
13 a little bit less, see the paragraph starting "We
14 did find an association"? Page 8.

15 A I'm looking for the page number.

16 Q Sorry. Let me give you a page number.
17 I'm not sure it has a page number.

18 A No, it doesn't.

19 Q Do you see the paragraph beginning "We
20 did find associations between overall cancer and
21 history of fibroid or ovarian cysts"? Do you see
22 that paragraph?

23 A Well, actually -- yes, I see that
24 paragraph.

1 Q If you'll look further, the sentence
2 beginning "This observation may suggest," do you
3 see that?

4 A Yes. Uh-huh.

5 Q And the paper says, "This observation
6 may suggest a possible additive or synergistic
7 effect on tumor- -- tumorigenesis influenced by
8 the proinflammatory milieu from an increased
9 burden in the number of benign conditions.
10 Increased risk of serous cancer, ovarian cancer,
11 women with other proinflammatory risk factors has
12 been reported -- reported, most notably in talc
13 users."

14 Do you see that?

15 A I do.

16 Q Is that the section you were thinking
17 of when you cited it in your report?

18 MS. BROWN:

19 Objection to the form.

20 A Yes, it is.

21 MS. O'DELL:

22 Q Let me ask you to -- a couple of other
23 final questions, Dr. Levy.

24 Excuse me. Give me one moment.

1 In regard to opinions in relation to
2 the pathology of ovarian tissue, would you defer
3 to a gynecologist or gynecologic oncologist or a
4 pathologist regarding that matter?

5 A Yes, of course.

6 Q You testified earlier today that you
7 relied on the Longo testing in -- in reaching
8 your opinions in this case.

9 MS. BROWN:

10 Objection to the form.

11 MS. O'DELL:

12 Q Did you rely on Dr. Longo's testing
13 in -- in reaching your opinions in this case?

14 A Yes. They were -- they were one of
15 the -- among many of the manuscripts we've been
16 discussing.

17 Q Yeah.

18 In fact, you cite Dr. Longo's report on
19 page 15 of your report. Is that right?

20 MS. BROWN:

21 Objection to the form.

22 A Yes.

23 MS. O'DELL:

24 Q And -- and in terms of Dr. Longo's

1 report, his findings of 37 of 56 historical talc
2 samples being positive for asbestos and 41 of the
3 42 samples tested containing fibrous talc,
4 was -- was that information you had prior to
5 reaching your opinions and finalizing your
6 report?

7 MS. BROWN:

8 Objection to the form.

9 A Yes.

10 MS. O'DELL:

11 Q And in relation to Dr. Crowley's report
12 regarding the fragrance chemicals, do you defer
13 to Dr. Crowley regarding his analysis of the
14 fragrance chemicals?

15 A Yes.

16 Q And did you rely on the opinions he
17 reached in relation to the fragrance chemicals in
18 reaching your opinions in this case?

19 A Yes. My -- my review of that just, in
20 addition to deferring it, was -- just made the
21 general -- or made the statement that I was in
22 general agreement with his opinions in those
23 matters, seeing as that's not a -- not an area of
24 expertise of mine.

1 Q And did you have the opportunity to
2 consider his report prior to finalizing your
3 report?

4 A I did.

5 Q I have nothing further. Thank you.

6 EXAMINATION

7 BY MS. BROWN:

8 Q Dr. Levy, would you take Exhibit 16
9 out, please, the FDA's response to the citizens
10 petition?

11 A I have it.

12 Q Counsel asked you some questions that
13 involved questions that I asked you. Remember
14 she asked you the lawyer for J & J didn't point
15 out the articles that were reviewed from 1980 to
16 2008 on page 4? Do you recall those questions
17 from plaintiffs' counsel?

18 A Yes.

19 Q Would you look at the last page of the
20 letter, page 6 of 7? I'd like to direct your
21 attention to the second sentence on this page
22 that begins "In consideration of your request."
23 Do you see that?

24 A I do.

1 Q And it states, "In consideration of
2 your request, we conducted an expanded literature
3 search dating from the filing of the petition in
4 2008 through January 2014. The results of this
5 search failed to identify any new compelling
6 literature data or new scientific data."

7 Do you see that?

8 A I see that.

9 Q And putting together, then, the
10 information from page 4 and page 6, you see that
11 the FDA considered literature from 1980 to 2014.
12 Is that correct?

13 MS. O'DELL:

14 Object to the form.

15 A Yes, that is correct.

16 MS. BROWN:

17 Q And what the FDA concluded, contrary to
18 your opinion here, Doctor, is that a cogent
19 biological mechanism by which talc might lead to
20 ovarian cancer is lacking; correct?

21 MS. O'DELL:

22 Object to the form.

23 A That's in this --

24 MS. BROWN:

1 Q Directing your attention to page 4,
2 number 4, the conclusion regarding a cogent
3 biological mechanism lacking. Do you see that?

4 MS. O'DELL:

5 Object to the form.

6 A Yes. I see where they -- they made the
7 statement that cogent biological mechanism by
8 which talc might lead to ovarian cancer is
9 lacking and that exposure to talc does not
10 account for all cases of ovarian cancer.

11 MS. BROWN:

12 Q Next, Doctor, do you rely on the
13 findings of the Hamilton article in forming your
14 opinions in this case?

15 A Similar to as we've discussed, in a
16 portion, yes.

17 Q You, Dr. Levy, cannot point us to a
18 single paper showing an inflammatory response
19 leading to ovarian cancer in humans from talc
20 use. True?

21 A There is -- I do not know of a single
22 paper that -- in a controlled fashion in humans
23 provided talc exposure that then was --
24 subsequently led to cancer in humans. That's

1 correct.

2 Q Controlled aside, you're not aware of
3 any observational case report, any kind of study
4 that shows talcum powder use causing an
5 inflammatory response leading to cancer in
6 humans; correct?

7 MS. O'DELL:

8 Object to the form.

9 A I would -- my review and development of
10 the biological plausibly -- plausible mechanism
11 examined literature that led to the conclusions
12 described in the report. I'm not aware of a --

13 The human-based studies were all case
14 cohort and -- or case-controlled and cohort
15 studies that showed an association with talc
16 exposure and cancer, but I'm not aware of a
17 direct study.

18 MS. BROWN:

19 Q There have been some reports of alleged
20 findings of talc in tissues or in other parts of
21 the body. Are you familiar with those?

22 A Yes.

23 Q And you're not aware of any one of them
24 demonstrating an inflammatory response that the

1 talc was causing in the body. True?

2 MS. O'DELL:

3 Object to the form.

4 A I'm aware of a number of studies that
5 looked at inflammatory response in model systems
6 and cell lines, and additional studies that
7 looked at inflammation in humans I believe were
8 referenced.

9 Certainly the Penninkilampi manuscripts
10 described inflammatory observations and -- as
11 well as the Buz'Zard and Lau were on human cells.

12 Q Dr. Levy, is it your testimony that the
13 Penninkilampi meta-analysis of prior
14 case-controlled studies demonstrated a
15 inflammatory response of -- from perineal use of
16 talc that led to ovarian cancer?

17 MS. O'DELL:

18 Object to the form.

19 A No. That's not my statement. It was
20 that those -- those papers reported an
21 inflammatory observation as part of those
22 studies.

23 MS. BROWN:

24 Q Not in the tissue from talc; right,

1 Doctor?

2 MS. O'DELL:

3 Object to the form.

4 A It would be those studies in the meta
5 review were not examining the tissue content for
6 talc. So they're unable to make that
7 determination.

8 MS. BROWN:

9 Q So we must be missing. I'm -- what I'm
10 asking you is for any study at all in the whole
11 world that shows that talcum powder in somebody's
12 body causing an inflammatory response that led to
13 ovarian cancer. Can you name one?

14 MS. O'DELL:

15 Object to the form.

16 A I mean, we've -- we've discussed a
17 number of studies that described the risk and
18 association of talc in ovarian cancer. But the
19 limitation of the -- of your question or the
20 limitation of the studies relative to your
21 question is those particular studies may not have
22 also assessed the inflammatory response or an
23 inflammatory response, given the nature of the
24 studies.

1 MS. BROWN:

2 Q Well, we got one. We got the Heller
3 study that purported to find talc in ovarian
4 tissue; right?

5 MS. O'DELL:

6 Object to the form. Different --

7 MS. BROWN:

8 Counsel, it's form, please.

9 MS. O'DELL:

10 Object to the form.

11 A Yeah. What was the -- the Heller
12 study, here it is.

13 Yes, I recall our discussion of this
14 paper.

15 MS. BROWN:

16 Q Right.

17 And this study reported that there was
18 no inflammatory response around the talc that
19 they claimed to have found in the ovarian tissue.
20 True?

21 A They make those statements in the
22 paper, but the -- the -- I would have some
23 concern with the histological methods, but I
24 would certainly defer to a pathologist in the

1 sense of being able to determine the both
2 presence of talc and the inflammatory response in
3 that.

4 Q So you have some critiques of the
5 Heller study. Is that fair?

6 MS. O'DELL:

7 Object to the form.

8 A I would say I would need a -- I would
9 need a -- a -- I would need a further evaluation
10 of the methodology for detecting both talc as
11 well as inflammation in the same materials using
12 the methods of the Heller paper.

13 MS. BROWN:

14 Q Are you aware of any other paper that
15 you think is methodologically superior that shows
16 the presence of talc in ovarian tissue exhibiting
17 an inflammatory response?

18 MS. O'DELL:

19 Object to the form.

20 A Well, we've discussed the rat studies.

21 MS. BROWN:

22 Q Human tissue. That's my question.

23 A Human --

24 Q Human tissue.

1 MS. O'DELL:

2 Actually, that wasn't your question.

3 But you've clarified it, so --

4 A The -- so you're excluding -- are you
5 excluding cell lines?

6 MS. BROWN:

7 Q Yeah. Human beings. Do you know of
8 any study like Heller in human beings that
9 purports to find talc in human women ovarian
10 tissue that shows an inflammatory response?

11 MS. O'DELL:

12 Objection to form.

13 A I'm not aware of a study showing that
14 specifically.

15 MS. BROWN:

16 Q Counsel asked you some questions about
17 nickel causing inflammation that leads to ovarian
18 cancer. Do you recall those?

19 MS. O'DELL:

20 Object to the form.

21 A No. I was asked if -- if heavy
22 metal -- or components like nickel have been
23 shown to have a potential inflammatory response.

24 MS. BROWN:

1 Q Uh-huh. Because you're not aware of
2 any published scientific literature that shows
3 heavy metals cause inflamma- -- inflammation that
4 leads to ovarian cancer; right?

5 A I wasn't asked to -- to review for
6 that. I would state that there's a number of
7 studies that show the role of metals --
8 particularly chromium -- and its -- and its
9 damaging effect on DNA, which I think by -- would
10 certainly have both an inflammatory as well as
11 carcinogenic effect.

12 Q And we're here on an issue of ovarian
13 cancer. And, as it relates to ovarian cancer,
14 you're not aware of any scientific support for
15 the proposition that heavy metals can lead to
16 inflammation that causes ovarian cancer. Fair
17 enough?

18 A Well, I was -- certainly, I was asked
19 to review the literature to develop a -- and
20 develop conclusions of that literature as it
21 related to a -- a potential or possible
22 biological mechanism.

23 In doing that, in part of that review,
24 we certainly made the observation that talc and

1 its components, as we discussed earlier, may
2 have -- there's the possibility of having
3 additional component effects, such as heavy
4 metals and their effects, asbestiforms and their
5 effects and the like; therefore, really
6 considering the complete components of the
7 product overall.

8 Q And, as it relates to the testimony you
9 just gave, you're talking about just a
10 theoretical possibility; right?

11 MS. O'DELL:

12 Objection to form.

13 A Sure. And, then, from that review
14 developing a -- a conclusion of a biologically
15 plausible mechanism.

16 MS. BROWN:

17 Q Has that conclusion been published in
18 the peer-reviewed literature, Doctor?

19 A No, it has not.

20 Q And, in fact, as you -- all of the
21 opinions that you gave here today, those opinions
22 have not been published in the peer review
23 literature. True?

24 MS. O'DELL:

1 Object to the form.

2 A Not at this time.

3 Q Counsel asked you some questions about
4 Dr. Longo. Do you recall that?

5 A Yes.

6 Q You've done nothing to validate the
7 findings that Dr. Longo writes about in his
8 reports. Is that fair?

9 A No, I have not done any experiments to
10 validate those findings.

11 Q Okay. Are you aware that some of the
12 samples that Dr. Longo tests and purports to find
13 asbestos were purchased off of eBay?

14 MS. O'DELL:

15 Misstates -- well --

16 A My review of the report, I was -- did
17 not include the -- I guess the specific history
18 of each of the samples.

19 MS. BROWN:

20 Q Do you understand that asbestos -- that
21 minerals like tremolite or anthophyllite, they
22 exist in both the asbestiform and nonasbestiform
23 way?

24 A I would defer to other experts on the

1 mineralogy of talc.

2 Q And whether what Dr. Longo is finding
3 in the samples that he tested is the asbestiform
4 or nonasbestiform variety of the minerals, you
5 would defer to others? Is that fair?

6 A I'd certainly defer to Dr. Longo.

7 Q And have you looked at any other
8 testing of the samples that Dr. Longo has tested?

9 MS. O'DELL:

10 Object to the form. Vague.

11 A Within the literature, there's -- there
12 was a number of tables describing testing,
13 described tests from previous testimony.

14 MS. BROWN:

15 Q Have you looked at the testing that
16 public health authorities like the FDA have done
17 on Johnson & Johnson's baby powder?

18 A I believe some of that was provided,
19 yes.

20 Q Are you relying on any finding of
21 asbestos from Dr. Longo in forming your opinions
22 here today?

23 A The --

24 MS. O'DELL:

1 Object to the form.

2 A The inclusion of the asbestos, again,
3 as -- as -- as we've discussed a few times today,
4 the conclusion I developed from the report were
5 not dependent or independent of any one or
6 another component of -- of the talcum powder.

7 As we discussed a bit ago, the presence
8 of asbestos as a known inflammatory mediator, as
9 well as potential carcinogen, I think just helps
10 lend additional support to the biological
11 plausibility of the mechanism. But I think that
12 biological mechanism is not dependent on the
13 presence of asbestos.

14 MS. BROWN:

15 Q Other than plaintiffs' expert,
16 Dr. Longo, are you relying on anything else to
17 support the potential for asbestos in baby
18 powder?

19 MS. O'DELL:

20 Object to the form.

21 A There's -- so I saw reference to
22 asbestos content in some of the other literature
23 that was reviewed during the time, and, so, there
24 were other publications that made mention of the

1 asbestos content in talc during the overall
2 review.

3 MS. BROWN:

4 Q Sitting here today, are you aware
5 whether or not that was Johnson & Johnson's
6 cosmetic talc?

7 MS. O'DELL:

8 Object to the form.

9 A I would have to look closely. I'm not
10 aware of that specifically.

11 MS. BROWN:

12 Q Counsel asked you some questions about
13 Dr. Crowley and whether or not you were relying
14 on the opinions he reached. Do you remember
15 those questions?

16 A I do.

17 Q What opinions did Dr. Crowley reach on
18 which you rely?

19 A Dr. Crowley performed an analysis of
20 the fragrance components and made assessments of
21 the individual chemical components and their
22 relationship to -- or I should say their -- their
23 inclusion on various lists for their -- their
24 chemical properties or safety. And in most -- in

1 the majority of cases, the chemicals were not
2 listed. In a number of cases, there were large
3 numbers of chemicals listed as either irritants
4 and, therefore, able to cause inflammation, or,
5 in a few cases, as potential carcinogens.

6 And, so, it was that review of that
7 information, similar to our discussions around
8 asbestos, that I included or agreed with his
9 opinions regarding that on the last paragraph or
10 close to the last paragraph of the report that
11 stated I was just in agreement that these -- that
12 those chemicals contribute to the inflammatory
13 properties observed.

14 Q Do you know in what quantity the
15 chemicals Dr. Crowley identifies are present, if
16 at all, in Johnson & Johnson's products?

17 A No. I wasn't asked to provide that
18 review. I would defer to Dr. Crowley's report
19 regarding any quantitative analysis of those
20 chemicals.

21 Q And, as it relates to your opinion,
22 Dr. Levy, it makes no difference whether
23 Dr. Crowley's list has ten chemicals in
24 Quantity X or five chemicals in Quantity Y. Your

1 opinion is independent of Dr. Crowley's findings.

2 Is that fair?

3 MS. O'DELL:

4 Objection to form. Vague.

5 A Well, my -- my -- my opinion, again,
6 similar to -- as we've been discussing that, it
7 considers the totality of the information
8 available, including Dr. Crowley's report, but
9 does not rely on any one specific report or
10 otherwise.

11 And, so, the -- again, restating
12 similar to the asbestos, the presence of
13 potential irritants as another component in
14 the -- in the product just provides additional
15 support for that inflammatory mechanism playing a
16 significant role.

17 MS. BROWN:

18 Q If none of the chemicals Dr. Crowley
19 identified were present in baby powder, would you
20 hold the same opinion of biological plausibility?

21 A I would.

22 Q If no asbestos was present in baby
23 powder, would you hold the same opinion on
24 biological plausibility?

1 A Yes.

2 MS. BROWN:

3 No further questions. Thank you.

4 MS. O'DELL:

5 I have just one follow-up.

6 Or do you have anything --

7 MR. FERGUSON:

8 Nothing further.

9 MS. O'DELL:

10 Excuse me. I'm sorry.

11 EXAMINATION

12 BY MS. O'DELL:

13 Q Dr. Crowley, are your opinions in this
14 case contained in your report as well as in the
15 testimony that you've given here today?

16 A You said Dr. Crowley.

17 Q Oh. Excuse me. Sorry. I had
18 Dr. Crowley on my mind.

19 Dr. Levy --

20 It's getting late in the day.

21 Dr. Levy, are your opinions in this
22 case expressed in your report and your testimony
23 today?

24 A Yes.

1 Q And do you hold those opinions to a
2 reasonable degree of scientific certainty?

3 A Yes.

4 MS. O'DELL:

5 I have nothing further.

6 MS. BROWN:

7 Thanks for your time, Doctor.

8 I think we're off the record.

9 VIDEOGRAPHER:

10 We're off the record. The time is
11 6 p.m.

12 (Deposition concluded at 6:00 p.m.)

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1 C E R T I F I C A T E

2

3 I do hereby certify that the above and
4 foregoing transcript of proceedings in the matter
5 aforementioned was taken down by me in machine
6 shorthand, and the questions and answers thereto
7 were reduced to writing under my personal
8 supervision, and that the foregoing represents a
9 true and correct transcript of the proceedings
10 given by said witness upon said hearing.

11 I further certify that I am neither of
12 counsel nor of kin to the parties to the action,
13 nor am I in anywise interested in the result of
14 said cause.

15

16

17

18

19 LOIS ANNE ROBINSON, RPR, RMR
REGISTERED DIPLOMATE REPORTER
CERTIFIED REALTIME REPORTER

20

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22

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24

1 E R R A T A P A G E

2

3 I, SHAWN LEVY, Ph.D., the witness herein,
have read the transcript of my testimony, and the
4 same is true and correct, to the best of my
knowledge, with the exceptions of the following
5 changes noted below, if any:

6 Page/Line Word(s) to be changed/reason Correct Word

7 _____

8 _____

9 _____

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23 SHAWN LEVY, Ph.D.

24

1 DECLARATION OF WITNESS

2

3 I, the undersigned, declare under penalty
4 of perjury that I have read the foregoing
5 transcript, and I have made any corrections,
6 additions, or deletions that I was desirous of
7 making; that the foregoing is a true and correct
8 transcript of my testimony contained herein.

9 EXECUTED this _____ day of _____,
10 2019, at _____, _____.
(City) (State)

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SHAWN LEVY, Ph.D.

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